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Stress And Health Interview For Primary Care Patients With Medically Unexplained Symptoms: A Randomized Trial

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STRESS AND HEALTH INTERVIEW FOR PRIMARY CARE PATIENTS WITH MEDICALLY UNEXPLAINED SYMPTOMS: A RANDOMIZED TRIAL

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CHAPTER 1: STUDY OVERVIEW

Somatic symptoms are the leading cause of outpatient medical visits (Kroenke, 2003b). One-third to one-half of outpatient primary care visits are for patients who present with elevated somatic symptoms that are not clearly explained by a disease or injury process—variously labeled medically unexplained symptoms (MUS), "functional" disorders, somatoform disorders (Kroenke, 2003a), or somatic symptom disorders (American Psychiatric Association, 2013). Other MUS consist of a syndrome or cluster of somatic symptoms for which the etiology is poorly understood, such as irritable bowel syndrome (IBS), fibromyalgia, chronic fatigue syndrome, temporomandibular disorder, and interstitial cystitis. These somatic syndromes often overlap and are similar in terms of psychiatric comorbidity, functional impairment, and family history (Aaron & Buchwald, 2001; Henningsen, Zimmermann, & Sattel, 2003; Kroenke & Rosmalen, 2006). All are characterized by physical symptoms that are not primarily explained by medical conditions (disease, injury, physiological perturbations), and all are associated with distress and impairment (Stuart & Noyes, 1999).

A history of trauma, stressful life events, or psychological conflict is common among patients with medically unexplained symptoms. Elevated trauma, stress, and emotional dysregulation have been found with patients who have fibromyalgia (Aaron et al., 1996; Merskey, 1989), IBS (Thompson et al., 1999; Whitehead, Bosmajian, Zonderman, Costa, & Schuster, 1988), pelvic pain (Mathias, Kuppermann, Liberman, Lipschutz, & Steege, 1996), headaches (Martin & Theunissen, 1993) multiple chemical sensitivity (Barsky & Borus, 1999), and chronic fatigue syndrome (Manu, Lane, & Matthews, 1989; Morrison, 1980). Indeed, emotional stressors have been found to precipitate, exacerbate, or prolong many functional somatic syndromes (Clauw & Chrousos, 1997; Waylonis & Perkins, 1994).

In primary care settings, which is where such presentations are initially and most commonly seen, the roles of stress and trauma are commonly ignored or minimized. The medical staff typically focuses on medical history, current signs and symptoms, laboratory tests and pharmacological interventions in the brief time that they have with the patients (Abbass, Kisely, & Kroenke, 2009; Kellner, 1991). Even psychologists in primary care also typically avoid directly focusing on trauma and conflict, in favor of assessments that focus on psychiatric diagnoses (e.g., anxiety, depression) or lifestyle behavior, and interventions that focus on behavior change or symptom management. The diagnosis of somatization is often made by indirect methods such as a patient checklist, clinical speculation, or exclusion when other biological causes are ruled out (De Gucht & Fischler, 2002). Similarly, existing treatment models focus on pain reduction and symptom management (Abbass et al., 2009; Kellner, 1991), but do not address stress or emotional dysregulation. Consequently, patients' basic problems of unresolved stressors, trauma, and emotional conflicts, and private struggles (e.g., secrets) are often overlooked in primary care (Escobar, Waitzkin, Silver, Gara, & Holman, 1998). This leads to prolonging patients' symptoms and distress and driving continued high utilization (Escobar, Swartz, Rubio-Stipec, & Manu, 1991). These problems contribute to the estimated $100 billion annually spent on U.S. healthcare (Barsky, Orav, & Bates, 2005). This high utilization renders the development of integrative assessment and intervention tools imperative to reverse this problem.

Research suggests that identifying and processing emotions connected to stressful experiences, conflicts, and secrets can improve pain and other symptoms. It appears that emotional avoidance and failure to process and resolve stressful experiences are core factors that prolong and maintain an excessive stress response, which contributes to physical symptoms. For

instance, a systematic review found that short-term intensive psychodynamic psychotherapy—an intervention that encourages patients to acknowledge and engage with avoided emotions and psychological conflicts—has many positive benefits for individuals with somatic symptom disorders (Abbass et al., 2009). Evidence also supports the benefits of a conceptually similar approach, written emotional disclosure, in a range of patient populations (Frattaroli, 2006; Smyth, 1998), including individuals with chronic pain (Lumley, Sklar, & Carty, 2012), such as fibromyalgia (Broderick, Junghaenel, & Schwartz, 2005), and chronic pelvic pain (Norman, Lumley, Dooley, & Diamond, 2004).

This research suggests that providing an experiential assessment interview that targets emotional and stressful experiences in primary care may be an important approach for patients with medically unexplained symptoms. This study tested how a single intensive interview focusing on stress, emotions, and emotional avoidance affects the attitudes and symptoms of primary care patients with medically unexplained symptom, compared to a waitlist, no-interview condition. It was hypothesized that individuals in the interview group would demonstrate greater awareness and endorsement of the links between their stress physical symptoms, compared to the waitlist control condition. It was also hypothesized that individuals in the interview group would experience more improvement in physical symptoms and psychological status, compared to those in the waitlist control condition.

CHAPTER 2: LITERATURE REVIEW

The experience of physical symptoms such as pain, fatigue, and dizziness, in the absence of disease or injury to fully explain them, is common, disabling, and costly (Abbass et al., 2009; Rief & Barsky, 2005). One-third to one-half of outpatient primary care visits are for patients with elevated somatic symptoms, medically unexplained conditions, "functional" disorders, somatoform disorders (Kroenke, 2003a, 2003b), with recent estimates ranging from 40% to 49% (Haller, Cramer, Lauche, & Dobos, 2015). This constellation of physically unexplained symptoms is sometimes referred to as "medically unexplained symptoms" (MUS). The broad category of MUS includes a variety of conditions including the somatoform disorders described in DSM-IV, somatization disorder, pain disorder, conversion disorder, and undifferentiated somatoform disorder. According to Abbass (2009), MUS entail individual physical symptoms, such as pain (e.g., low back, joint, chest, abdominal, headache) and nonpain (e.g., fatigue, dizziness, palpitations) complaints. Others posit that MUS consist of a cluster of somatic symptoms for which the etiology is poorly understood, such as irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, temporomandibular disorder, and interstitial cystitis. These somatic syndromes often overlap and are similar in terms of psychiatric comorbidity, functional impairment, and family history (Aaron & Buchwald, 2001; Henningsen et al., 2003; Kroenke & Rosmalen, 2006). All are characterized by physical symptoms that are not primarily explained by medical conditions (disease, injury, physiological perturbations), and all are associated with distress and impairment (Stuart & Noyes, 1999).

Medically unexplained somatic symptoms are the leading cause of outpatient medical visits (Kroenke, 2003b). The prevalence rate of MUS in primary care is high, ranging from 30% to 60% of primary care patients (Stuart & Noyes, 1999). Patients with MUS also have a high

prevalence in specialist care and are responsible for a significant proportion of disability in the workforce (Barsky et al., 2005; Wessely, Nimnuan, & Sharpe, 1999). Clinically significant somatization or unexplained medical symptoms often lead to excessive healthcare use, costing the U.S. healthcare system an estimated $100 billion annually (Barsky et al., 2005).

Prevalence of psychosocial distress in patients with MUS

In healthcare settings, medically unexplained symptoms are likely related to psychological stress and often result in help-seeking behaviors (Kroenke, Spitzer, & Williams, 2002). Numerous studies suggest that early adverse life experiences contribute to the development of somatization in adulthood (Stuart & Noyes, 1999). In particular, childhood trauma, including sexual abuse, physical abuse, emotional abuse, and neglect, have been linked with somatization in adults (Sansone, Wiederman, & Sansone, 2001; Spertus, Yehuda, Wong, Halligan, & Seremetis, 2003), and a wide range of symptoms for which there is no medical explanation, including chronic pain (Green, Flowe-Valencia, Rosenblum, & Tait, 2001), headaches (Bendixen, Muus, & Schei, 1994), gynecological complaints (Cunningham, Pearce, & Pearce, 1988), gastrointestinal symptoms (Bass, Bond, Gill, & Sharpe, 1999), and musculoskeletal symptoms (Bendixen et al., 1994).

A number of studies have documented the relationship between MUS and psychiatric disorders. Significantly elevated prevalence rates of psychiatric symptoms and diagnoses were found in patients with fibromyalgia (Aaron et al., 1996; Merskey, 1989), irritable bowel syndrome (Thompson et al., 1999; Whitehead et al., 1988), patients with multiple chemical sensitivities (Barsky & Borus, 1999), and chronic fatigue syndrome (Manu et al., 1989; Morrison, 1980). Patients with MUS have increased rates of depression and anxiety (Bass, Peveler, & House, 2001; Katon, Sullivan, & Walker, 2001), and distressing somatic symptoms

are also increased 2- to 3-fold in patients with depressive and anxiety disorders (Kroenke, 2003a; Sha et al., 2005). The mechanism of this association remains unclear and subject to further investigation.

Theories about somatization, stress and health

These links between somatic symptoms and psychiatric disorders are indicative of the role of psychological factors, particularly negative emotions, in inducing or exacerbating somatic symptoms. Substantial research suggests that stressful major life events play a role in amplifying bodily symptoms, and emotional stressors have been found to exacerbate or precipitate many functional somatic syndromes (Clauw & Chrousos, 1997; Waylonis & Perkins, 1994). Research shows the coexistence of somatic and depressive symptoms (Herrman et al., 2002; Simon, VonKorff, Piccinelli, Fullerton, & Ormel, 1999; Turk, Okifuji, & Scharff, 1995).

In models of central sensitization (CS), individuals experience excessive sensitivity to both painful and nonpainful stimuli, a common symptom shared among individuals with medically unexplained syndromes (e.g., fibromyalgia, chronic pelvic pain, headaches). Yunus (2008) described CS, attributing it to alterations in the central nervous system (Yunus, 2008). A review of studies confirms the links between life stress and CS (Yunus, 2007) and presents associations between childhood abuse and CS, such as fibromyalgia and chronic fatigue syndrome (Van Houdenhove et al., 2001), IBS (Scarinci, McDonald-Haile, Bradley, & Richter, 1994), and headaches (Golding, 1999). Childhood adverse experiences may promote long-lasting neuronal plasticity that causes both physical and psychological symptoms, as well as central sensitization among adults. Finally, trauma has been linked to many CS syndromes (Banic et al., 2004; Sterling, Jull, Vicenzino, & Kenardy, 2004).

Within the trauma literature, theorists have proposed mechanisms by which trauma can affect physical symptoms. Andreski and colleagues suggest that among individuals with posttraumatic stress disorder (PTSD), psychosocial stress may increase personal vulnerability toward experiencing physical symptoms (Andreski, Chilcoat, & Breslau, 1998), potentially through the action of inflammatory mediators (Banic et al., 2004; Sterling et al., 2004). It has also been suggested that neurobiological changes, increased physiological arousal and poor health behaviors in the aftermath of trauma paves the way for somatization (Van Ommeren et al., 2002). Alternatively, some have argued that the medical problems or physical symptoms are often manifestations of emotional conflicts (O'Donohue & Levensky, 2006), and some of these emotional conflicts are unconscious and manifest as physical symptoms such as headaches, gastrointestinal problems, and pain (Cunningham et al., 1988).

Experiential and emotional avoidance

Emotional conflict may lead individuals to become dysregulated, and often these individuals experience difficulty in managing stressful situations and are more vulnerable to the detrimental effects that stress can have on the body. These individuals often avoid emotional experiences due to the threat or fear of the experience or expression of emotion, which then may lead to dysregulation. Experiential avoidance refers to a general tendency to avoid any aspect of internal experience evaluated as aversive, which may or may not include those internal experiences associated with a traumatic event (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). It appears that experiential avoidance mechanisms, including emotional suppression, inhibition, and failure to process and resolve stressful experiences, are core factors that prolong and maintain an excessive stress response, which contributes to physical symptoms through various pathways (e.g., brain-based augmentation, muscular tension, somatic preoccupation). For

example, a study aimed at identifying stress-mechanisms found that emotional avoidance negatively influences the physiology, psychology, and social struggles of patients by causing the activation of the sympathetic nervous system. In turn, sympathetic activation causes the body to be hypersensitive to stress and adversely affects the ability to relax and sleep deeply, thus reducing parasympathetic activity (Lind, Delmar, & Nielsen, 2013).

It is plausible that experiential avoidance results in patients losing contact with their deeper needs, vulnerability, and primary emotions during stressful times, responding to stress physiologically and behaviorally rather than emotionally and relationally (Lind et al., 2013). A review by Lind and colleagues (2013) shows associations between diagnoses of fibromyalgia or somatoform disorder with lack of physical affection and poor emotional relationships with parents, as well as physical quarrels between parents (Imbierowicz & Egle, 2003). Research also finds a significant association between somatoform disorders and suppression of affect (Gündel et al., 2008; Stoeter et al., 2007), and decreased body and emotional awareness (Mehling et al., 2013; Subic-Wrana, Beutel, Knebel, & Lane, 2010).

This body of literature underscores the critical role of emotion processes, particularly emotional avoidance and suppression, in inducing or exacerbating somatic symptoms. Unfortunately, existing assessment and treatment models, particularly in primary care, do not address the unresolved stress and emotional dysregulation that result in physical symptoms.

How are stress and emotional processes currently assessed in primary care?

One-third to one-half of outpatient primary care visits are for patients with elevated somatic symptoms, medically unexplained conditions, “functional” disorders, or somatoform disorders (Kroenke, 2003a, 2003b). Despite this high prevalence of somatization in medical settings, it often remains unrecognized (Morriss et al., 1998) or poorly diagnosed. This lack of

recognition results in unnecessary testing, admission, surgery, medication, and patient suffering (Gask et al., 1991). The diagnosis of somatization is often made by indirect methods such as a patient checklist, clinical speculation, or exclusion when other biological causes are ruled out (De Gucht & Fischler, 2002). Several screening tools have been developed and utilized in medical and research settings. These include screening for elevated somatic symptoms with the Patient Health Questionnaire-15 (Kroenke et al., 2002); screening for somatoform symptoms (SOMS; Fabião et al., 2010), the Schedule for Evaluation of Persistent Symptoms (SEPS; Helen et al., 2013), International Classification of Diseases-10 (ICD-10; WHO), and the General Health Questionnaire (Goldberg & Williams, 2000). Other models include estimating the likely prevalence of medically unexplained symptoms and severe medically unexplained symptoms in a primary care practice when existing patient electronic records suggest increased treatment seeking and multiple diagnoses of medically unexplained symptoms (Morriss, Lindson, Coupland, Dex, & Avery, 2012). Clearly, these tools do not directly assess the sources of stress, emotional avoidance, and primary emotions that underlie some of these physical symptoms, rendering the evaluations lacking.

Similarly, existing treatment models focus on pain reduction and symptom management, but they do not address stress or emotional dysregulation (Abbass et al., 2009; Kellner, 1991). In primary care settings, which is where such presentations are most commonly seen, the role of stress and trauma is commonly ignored or minimized in patient interviews by the medical staff. Instead, perhaps understandable given the brief time they have with patients, medical staff typically focus on biological illness, laboratory tests and subsequent pharmacological interventions (Abbass et al., 2009; Kellner, 1991). Even psychologists in primary care typically do not directly focus on trauma and conflict, in favor of assessment that focuses on psychiatric

diagnoses or distress (e.g., anxiety, depression), lifestyle behavior, and brief symptom management interventions. Consequently, patients' basic problems of unresolved stressors, trauma, and emotional conflicts, including secrets, are often overlooked in primary care (Escobar et al., 1998), and the entire system suffers from excessive costs and utilization (Escobar et al., 1991). This problem renders the development of integrative assessment tools imperative to reverse this problem.

Additionally, there may be a tacit understanding by the patient that psychological symptoms are threatening for the physician and cannot be handled in a medical context, so the patient stays on safe ground by offering physical symptoms (Taylor & Mann, 1999). We need to understand more about patients' beliefs concerning their symptoms, to what causes they attribute symptoms, and what treatments they believe are possible. We also need to understand that patients may fear that sharing such beliefs lead them to be sent elsewhere, away from the medical world.

Health attitudes and readiness to change

There has been little emphasis on the measurement of illness beliefs and attributions in somatization research, despite the evidence from cognitive psychology that beliefs influence behavior (Bandura, 1986). Generally, attributions can either be normalizing (e.g., "I feel ill because I'm overworking and unfit", somatic (e.g., "I feel ill because my system has been weakened by a virus"), or psychological (e.g., "I feel ill because I'm depressed") (Burton, 2003). Studies of primary care patients (Sensky, MacLeod, & Rigby, 1996) and patients with high health anxiety (Kirmayer & Robbins, 1996) suggest that normalizing attributions occur less often than in controls; furthermore, this lack of normalizing attributions, which might be viewed as a form of catastophizing, likely elicits sickness behavior. Others posit that patients appear to

have clear views about their symptoms and view their own experience of the symptoms as at least as important as a doctor's opinion about them. Salmon and colleagues suggest that patients perceive doctors as denying the validity of the patients' symptoms when they present with medically unexplained symptoms (Peters, Stanley, Rose, & Salmon, 1998), but when doctors develop tangible and non-blaming models about the illness, patients are then able to accept medical opinion (Salmon, Peters, & Stanley, 1999).

Attributional styles appear to be rigid and difficult to change, except among patients who are young, single, and with short illness duration (García-Campayo, Larrubia, Lobo, Pérez-Echeverría, & Campos, 1997). Changing specific attributions about symptoms appears to be important in effecting improvement. A study by Van Dulmen and colleagues (1996) found that when patients with IBS continue to attribute their symptoms to a somatic abnormality even after such abnormalities have been ruled out, their use of medical healthcare is likely to increase. Also, the physicians' referral behavior appears to strengthen these dysfunctional somatic attributions. These behaviors can be avoided by handling cognitions and anxiety specifically during medical consultations in primary care (Van Dulmen, Fennis, Mokkink, & Bleijenberg, 1996). Changing specific attributions about symptoms appears to be important in effecting improvement (Van Dulmen et al., 1996).

Another dimension to consider in understanding patients' attitudes and motivations is patients' readiness for change. One of the theories purported to assess readiness and motivation to change is the transtheoretical model, which posits that health behavior change involves progress through six stages: precontemplation, contemplation, preparation, action, maintenance, and termination. Applied research has demonstrated dramatic improvements in recruitment, retention, and progress using stage-matched interventions and proactive recruitment procedures

(Prochaska & Velicer, 1997). It is important to consider patients' stage of change in relation to their attitudes and beliefs about their symptoms with respect to adopting a psychological rather than biological model of symptoms and treatment options. Prochaska and colleagues (2008) describe 10 processes of change that are divided into cognitive or experiential processes and behavioral processes. The cognitive/experiential processes are best suited for patients in the early stages of change, whereas the behavioral processes are best suited for the later stages of change. I hypothesize that the majority of patients in the current study will be in the early stages of change (i.e., precontemplation and contemplation) in shifting their awareness of the link between their stress, psychological conflict, and health; thus, this dissertation will focus on the cognitive/experiential processes. The cognitive/experiential processes involve: 1) consciousness raising, 2) dramatic relief, 3) self-reevaluation, 4) environmental reevaluation, and 5) self-liberation. Of particular importance to this dissertation is consciousness raising, which is aimed at increasing awareness about the causes and implications of behaviors, and dramatic relief, which is aimed at increasing emotional experiences or responses. Based on this theory, it will be important for assessments in primary care settings to incorporate increasing awareness of the causes and effects of behavior, and focus on increasing emotional experiences. For instance, patients with medically unexplained symptoms who insist that they do not have any stress or do not acknowledge any links between stress and their physical symptoms may fall into the pre-contemplation stage. Hence, intervention techniques with these patients would focus on psychoeducation and awareness raising to trigger their motivation to change their attitudes. On the other hand, patients with MUS who acknowledge the role of stress in perpetuating their symptoms would likely benefit from an action-oriented approach like stress management or skills training to reduce pain and discomfort. Hence, it is important to assess patients' current

beliefs and their *flexibility* and *readiness* for change in their attitudes and beliefs about their symptoms. This approach will help us determine the techniques best suited for their stage of change.

Effectiveness of emotion-focused treatment modalities

The avoidance of emotions and thoughts may be a common coping strategy among individuals dealing with psychosocial distress or interpersonal conflict. This behavior can result in distress, helplessness, and physical symptoms, which lead to medical treatment seeking. Research suggests that identifying and processing emotions connected to stressful experience, conflicts, and secrets can improve pain and other somatic symptoms. In addition, a range of evidence supports the view that people will disclose their stressful experiences when asked, and that such disclosure, along with emotional expression, will help patients improve their symptoms.

Short-Term Psychodynamic Psychotherapy

Short-term psychodynamic approaches have been advanced as a way to increase emotional awareness and thereby decrease physical symptoms. This approach involves examining unconscious motivation, difficulty describing and expressing emotion, and broadly, making unconscious phenomena conscious by activating the underlying conflicts the individual is facing (Abbass et al., 2009). Abbass (2009) proposes that when emotions become too intense or conflicted for an individual, anxiety, as well as defenses against that anxiety, (e.g., suppression or avoidance of emotion) occur. Suppressing and avoiding emotions can lead to an exacerbation of physical symptoms, and ongoing avoidance serves to maintain those symptoms, which is a common process in pain patients. Often, the suppression of emotions and process of somatization is unconscious to patients and, therefore, it is important to help the patient develop

a greater understanding and experiencing of their emotions (Abbass et al., 2009). To this end, research has shown that patients with hypertension, migraine, irritable bowel syndrome, and other conditions internalize anger and thus increase their somatic problems (Roter & Ewart, 1992; Venable, Carlson, & Wilson, 2001). Blocking and inhibiting of emotions, including anger, appears to be a common finding in somatizing patients.

Short-term psychodynamic psychotherapy (STPP) is an intervention that encourages patients to acknowledge and engage with avoided emotions and psychological conflicts. A systematic review of 23 studies of short-term psychodynamic psychotherapy found generally significant and sustained benefits for somatic symptom disorders (Abbass et al., 2009). Short-term psychodynamic psychotherapy has been shown to reduce healthcare utilization in treating patients with MUS, including reductions in total costs, medication costs, disability, hospital, and physician use (Abbass, 2003).

Written Emotional Expression

Research shows that emotional exposure-based interventions can improve pain symptoms, and some studies suggest that *expressing* rather than avoiding negative emotional experience has benefits for reducing pain. For example, writing repeatedly about private stressful experiences and avoided emotions (i.e., written emotional disclosure, or expressive writing), has shown benefits in controlled studies for a range of populations and outcomes (Frattaroli, 2006; Smyth, 1998). Written emotional disclosure has been shown to improve immune functioning (Esterling, Antoni, Fletcher, Margulies, & Schneiderman, 1994; Petrie, Booth, Pennebaker, Davison, & Thomas, 1995), respiratory status (Smyth, Stone, Hurewitz, & Kaell, 1999) and reduce distress in women with breast cancer (Stanton et al., 2002). With respect to chronic pain, emotional disclosure led to improved health status in patients with rheumatoid arthritis (Smyth et al., 1999),

chronic pelvic pain (Norman et al., 2004), and fibromyalgia (Broderick et al., 2005).

Our laboratory has contributed extensively to this literature, and we have also demonstrated that a brief group therapy intervention that enhances anger awareness and expression improves chronic headaches (Slavin-Spenny, Lumley, Thakur, Nevedal, & Hijazi, 2013). Lumley and colleagues (2008) conducted an emotional exposure pilot intervention for patients with fibromyalgia and found a moderate to large impact on stress symptoms, symptom impact, and emotional distress, and a small to moderate effect on pain and disability at 3-month follow-up. Additionally, a study by Hsu and colleagues (2010) showed that an affective self-awareness intervention improves pain, tenderness, and self-reported physical function for at least 6 months in women with fibromyalgia compared to waitlist control (Hsu et al., 2010). This study suggests the value of interventions targeting emotional processes in fibromyalgia. Collectively, these studies suggest that emotional exposure therapies can be effective in improving psychological and physical health.

Diagnostic interviewing

In 2005, Abbass introduced the notion of emotion-focused interviewing in a healthcare setting. He suggested that in order for clinicians to diagnose somatization disorders, they should ask about specific recent events to activate emotions and consequent somatic symptoms during an emotion-focused interview. Throughout this process, the clinician identifies patterns of particular somatic symptoms related to stressful life events, and helps the patient identify and recognize them. If a patient has difficulty, Abbass (2005) suggests that a clinician could discuss defenses used for emotional avoidance with the patient during their interaction. At the end of the interview, findings are reviewed with the patient, in a similar fashion as one would share a laboratory finding, such as a blood test. If the interviewer finds that symptoms increase with an

emotional focus, and decrease when emotions are not the focus, then the diagnosis is likely somatization, and emotion-focused psychotherapy is recommended (Abbass, 2005).

For an emotion-focused diagnostic interview to be effective, research suggests that the patient's understanding must be considered. Smith and colleagues (2003) have developed a multidimensional treatment plan aimed at achieving patient understanding and new ways of thinking about somatic symptoms. This plan includes first recognizing that an organic cause was not found, rendering further testing and consultation unnecessary. Next is facilitating an understanding that their somatic symptoms are real, and that stress, depression and anxiety contribute to them. Lastly, patients understand that although medications might help, cure is unlikely but improvement is possible.

Taken together, these various theories, models, and studies suggest that stressful life experiences, emotional avoidance, and failure to process negative emotions related to these experiences contribute to physical symptoms. To fill a gap in the current literature and enhance clinical outcomes for the substantial number of patients in primary care who are so afflicted, novel assessment approaches need to be developed. These approaches would aim to both influence patients' understanding of the links between their stress and symptoms and to target underlying processes that may improve their physical symptoms.

Goals of current study

These various theories and lines of research show that stress and emotional difficulties are common in primary care and contribute to physical symptoms, and that people will disclose their stressful experiences when asked. The disclosure, along with emotional expression, will help patients see the links between emotional processes and symptoms and improve their health. Hence, this study tested the feasibility and acceptability of providing an experiential assessment

interview that targets emotional and stressful experiences in a primary care setting. I proposed that helping an individual first identify the links between their stress and symptoms would increase their awareness and endorsement of the link between stress and physical symptoms, including a willingness to engage in stress management techniques. Second, I proposed that helping raise patients' awareness about their symptoms, followed by an experience and expression of unexpressed emotions would reduce their physical symptoms and psychological distress (Figure 1).

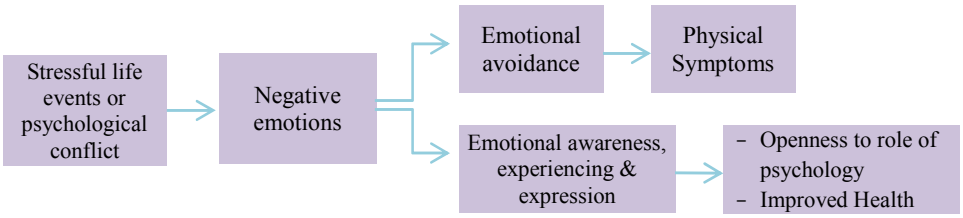


Figure 1. Proposed Model

In this study, patients with medically unexplained symptoms were recruited from the Crittenton Family Medicine Clinic, randomized to the life-stress interview immediately or to a waitlist control condition, and completed baseline and follow-up questionnaires.

Hypotheses

The two primary hypotheses regarding patients' physical health and symptom attributions:

1. Patients in the life-stress interview group would demonstrate improvements in their physical health from baseline to follow-up, compared to those in the waitlist control condition.
2. Patients in the life-stress interview group would demonstrate changes in their symptom attributions from baseline to follow-up:

a. Patients in the life-stress interview group would score higher on psychological attributions, compared to those in the waitlist control condition.
b. Patients in the life-stress interview group would score lower on somatic attributions, compared to those in the waitlist control condition.
c. Patients in the life-stress interview group would score lower on environmental attributions, compared to those in the waitlist control condition.

Secondary hypotheses regarding patients' physical status, psychological functioning, and motivation for change:

3. Patients in the life-stress interview group would demonstrate improvements in their pain severity and interference, from baseline to follow-up, compared to those in the waitlist control condition.
4. Patients in the life-stress interview group would demonstrate improvements in their overall psychological symptoms including depression, anxiety, and interpersonal sensitivity from baseline to follow-up, compared to those in the waitlist control condition.
5. Patients in the life-stress interview group would demonstrate improvements in their sleep problems from baseline to follow-up, compared to those in the waitlist control condition.
6. Patients in the life-stress interview group would demonstrate improvements in their life satisfaction from baseline to follow-up, compared to those in the waitlist control condition.
7. Patients in the life-stress interview group would demonstrate changes in their motivation for change from baseline to follow-up:

a. Patients in the life-stress interview group would score lower on pre-contemplation scores, compared to those in the waitlist control condition.

b. Patients in the life-stress interview group would score higher on action scores, compared to those in the waitlist control condition. No hypotheses were specified for contemplation or maintenance scores.

Overall, if the hypothesized results are observed, effective stress assessment and intervention procedures can be created and integrated in primary care to examine both the acceptance of stress-physical symptom connections, and readiness to address stress status among patients with elevated physical symptoms. Ultimately, a culture of considering emotional factors can be woven into practice, weakening resistance to the idea that emotions and health, mind and body, are tightly bound and should be addressed in the primary care setting.

CHAPTER 3: METHOD

Participants

Participants were 80 men and women who had unexplained somatic symptoms and were patients at the Crittenton Family Medicine Clinic in Rochester Hills, Michigan. However, 5 patients were administratively removed from the study, as described later, resulting in a final sample of 75 who were followed and analyzed. All patients endorsed at least a moderate level of physical symptoms (>10 on PHQ-15) at screening. Most of the patients (~75%) were recruited in the waiting room, about 20% were referred by their primary care physician, and about 5% were referred by the psychologist at the clinic. Of 75 patients in the study, 16% had a diagnosis of fibromyalgia (n = 12), and 12% had a diagnosis of irritable bowel syndrome (n = 9).

The majority of patients were women (86.7%); and their mean age was 39.2 years (SD = 13.66), ranging from 18 to 64 years. Most identified themselves as European American (78.7%), whereas 16% identified as African American, 1.3% as Middle Eastern or Arab, and 4% as Other. Almost one-third of the participants were never married (30.7%), whereas over one-third were either married (24%) or living with their significant other (14.7%). The other participants were divorced (26.7%), separated (1.3%) or widowed (2.7%). Participants had a mean education of 14.0 years (SD = 1.8); that is, slightly over 2 years of college, with 3.8% of the sample with less than high school degree, and 28% of the sample with a bachelor's degree or higher.

Procedure

The study was registered on clinicaltrials.gov (NCT02151500). Patients were recruited during routine visits either in the waiting room or when referred by their providers. All patients were screened using the Patient Health Questionnaire-15 (PHQ-15) (Kroenke et al., 2002), and those patients who scored above 10 (moderate range) were contacted by a research assistant to

further determine their eligibility, prior to the patient leaving the clinic. The research assistant asked patients who scored above the cutoff additional detailed screening questions. Exclusion criteria included the presence of disease or injury (e.g., autoimmune disease, bodily injury, serious infection, cancer, heart disease, COPD, post-stroke, expecting major medical procedures in the next two months) that could account for the elevated physical symptoms, or various conditions that could interfere with the interview (non-English speaking, psychosis, dementia, mental impairment), or exclusion by the medical staff for other reasons (e.g., presumed drug seeking, legal problems).

Those potential participants who met study criteria and remained interested were invited to review the study procedures and provide written, informed consent. Participants received an email later that day to complete baseline questionnaires using an on-line system (Qualtrics). Questionnaires assessed participants' health and functioning, psychological distress, life satisfaction, and attitudes toward the role of psychological factors in their health. Once they completed their baseline questionnaires, participants were contacted by phone, reminded of the study requirements, and (assuming their continued interest) randomized into the experimental or control conditions. Both the interviewer and patients were blind to condition assignment until this time. The randomization scheme was created with randomization.com, prior to recruitment, by someone not involved with the patients in the study. Randomization was stratified by participant gender and interviewer, occurred in randomized blocks of 3 or 6, and occurred in a 2:1 ratio (experimental: control); this ratio was used to ensure a larger sample in the experimental condition, which would support later analyses of interview content and predictors or responses to the interview.

Participants randomized to the experimental group were contacted by phone to schedule their interview and typically had their interview at the clinic within a week of randomization. Six weeks after randomization, all participants received a reminder phone call and a link to complete the follow-up questionnaires online. These measures were the same measures that participants filled out at baseline; however, reactions to and satisfaction with the interview were added for those patients in the interview condition. Participants who were in the waitlist control group also completed follow-up questionnaires 6 weeks after randomization. After follow-up, participants in the control condition were given the opportunity to participate in the experimental interview. Participants received $10 for completing the baseline questionnaires, $20 for completing the interview session, and $20 for completing the follow-up questionnaires.

Emotion-focused Stress Interview

Two doctoral students in clinical psychology conducted screenings and the interview sessions (MZ, n = 31, 65%; HD, n = 16, 35%). Interviewers were trained and supervised by a licensed clinical psychologist (MAL) with extensive experience in emotional processing interventions. Sessions were audio recorded to facilitate supervision and fidelity checks, as well as provide data for secondary analyses of interview content. The interview session was conducted in an individualized format, and lasted about 90 minutes in an exam room at the clinic. At the beginning and end of the interview session, participants completed a brief measure of their mood and symptoms, in addition to their reactions to and satisfaction with the interview. Participants' blood pressure was also measured at the beginning and end of the interview session. These latter measures are not included in this dissertation.

The goals of the interview were to help patients: a) disclose their stressful experiences and emotional conflicts, which might be contributing to their symptoms; b) learn about

associations between their stress and physical symptoms; and c) learn about the potential value of experiencing and expressing their emotions related to these stressful situations. The interview occurred in a private room in the clinic and included four phases:

1. Review of symptoms over life course (≈10 minutes): During the initial phase of the interview, participants were interviewed about their medical history, including the onset and development of their symptoms over their life course.
2. Review of life stress and emotional conflict (≈30 minutes): This entailed surveying participants' psychosocial history of stressful life events. The interviewer asked the participant about their conflicts over relationships and identified areas of emotional and relational conflict for the participant. The interviewer also inquired about other stressful events in participants' lives, including internal struggles and secrets they harbor. At this point, the interviewer and patient typically identified a key conflicted interpersonal relationship for the patient.
3. Experiential and expression exercises (≈40 minutes): During the third phase of the interview, the interviewer led the participant through a series of emotional experiencing and expression exercises, using the study model (Appendix E), which target the two core emotional / relational processes that are typically conflicted: dominance (power, agency, including anger) and attachment (love, sadness, guilt, and other connecting emotions). These exercises encouraged participants to experience affect in their body, and then express these emotions in the room, with vocal tone, facial, and physical expression. We have used this expression component in several other studies (of fibromyalgia, headaches, irritable bowel syndrome), and it is based on the intensive interview

successfully used by Abbass (Abbass, 2005) and Dr. Schubiner's approach to treating chronic pain in his clinical practice.

4. Summary and Discussion (≈10 minutes): Finally, the participants discussed their experience with the interviewer, including what they learned about their stress, emotions, and links to their symptoms. The interviewer provided feedback of her observations of the source and role of stress in the participant's life, and patients took home a copy of the study model discussed during session (Appendix E).

Control Condition

After baseline assessment, participants in the control condition engaged only in their standard care. After completing the follow-up assessments, these patients were given the opportunity to participate in the emotion-focused stress interview.

Measures (see Appendix B, p. 64)

There were two primary outcomes; one reflecting change in physical health status, and the other reflecting change in attributions about the role of psychological factors in patients' symptoms.

Somatic symptom severity. The 15-item Patient Health Questionnaire (PHQ-15; Kroenke, Spitzer, & Williams, 2002) was used to assess somatic symptoms over the last week. This measure is useful in screening for somatization and in monitoring somatic symptom severity in clinical practice and research. It contains 15 somatic symptoms or symptom clusters that account for more than 90% of the physical complaints reported in the outpatient setting (Van Ravesteijn et al., 2009). For each somatic symptom, participants are asked, "During the past week, how much have you been bothered by any of the following problems?" The three scoring options are coded as 0 (*not bothered at all*), 1 (*bothered a little*), or 2 (*bothered a lot*). Totals of the 15 items

are calculated, and scores of 5, 10, and 15 represent cut-points for low, medium, and high somatic symptom severity, respectively. The scale demonstrates good test-retest reliability, internal validity, and convergent and discriminate validity (Kroenke et al., 2002). This measure was used for screening, and as one of the primary outcomes at baseline and follow-up. In this sample, the PHQ-15 had relatively low reliability at baseline ($\alpha = .59$) and adequate reliability at follow-up ($\alpha = .79$).

Symptom attribution. The Symptom Interpretation Questionnaire (Robbins & Kirmayer, 1991) was the other primary outcome and assessed somatic, psychological, and normalizing causes of somatic symptoms. The SIQ consists of 39 items measuring the degree to which participants attribute their symptoms in three areas: psychological ("if I had a prolonged headache, I would probably think it was because, I am emotionally upset"), somatic ("if I had a prolonged headache, I would probably think it was because there is something wrong with my muscles, nerves or brain"), or normal/environmental ("if I had a prolonged headache, I would probably think it was because a loud noise, bright light or something else had irritated me"). The SIQ yields scores on three subscales corresponding to the three areas of attribution. All items are rated on a scale of 0 (*not at all*) to 3 (*a great deal*). Higher scores on each subscale indicate higher levels of symptom attribution in that area. The scale demonstrates adequate reliability (α's for the psychological (13 items), somatic (13 items), and normalizing scales (13 items) were .86, .71, and .81, and test–retest correlations over a 4-month period were .63, .60, and .65), respectively (Robbins & Kirmayer, 1991). In this sample, SIQ had good reliability at baseline (psychological $\alpha = .86$; somatic $\alpha = .84$; and normalizing $\alpha = .79$) and at follow-up (psychological $\alpha = .91$; somatic $\alpha = .78$; and normalizing $\alpha = .86$).

Secondary Outcomes:

There were several secondary outcomes reflecting symptom change (physical symptoms, psychological functioning) and attitudinal measures assessing motivation for change.

Pain severity and pain interference. This was assessed using the 16-item Brief Pain Inventory (Cleeland & Ryan, 1994). The BPI includes 4 ratings of pain intensity and 12 ratings that cover the impact of pain on functioning. Intensity is recorded on a scale from 0 (no pain) to 10 (pain as bad as you can imagine). Pain is assessed as "current" and as "highest," "lowest," and "average" during the past week, and calculated by averaging the four pain rating items. Pain interference is assessed in terms of how much the patient's pain interferes with a range of activities, on a scale from 0 (*no interference*) to 10 (*interferes completely*), and calculated by averaging the 12 interference items. The BPI has acceptable psychometric data; coefficient alpha of .87 for the four pain intensity items and .91 for the interference scale. In this sample, pain severity and pain interference had excellent reliability at baseline (α = .89 and α = .96) respectively, and at follow-up (α = .90 and α = .97) respectively.

Psychological symptoms. This was assessed with the widely used Brief Symptom Inventory (Derogatis & Melisaratos, 1983). The BSI consists of 53 items that measure a variety of psychological symptoms experienced over the past 7 days. Each item is rated on a scale of 0 (*not at all*) to 4 (*severely*), with higher scores indicating more psychological symptoms. To reduce patient burden and focus on constructs relevant to this population, only the depression, anxiety, and interpersonal sensitivity subscales were given, which also yield an overall symptom severity, resulting in a shortened BSI that is 16 items. This measure has well-established reliability, and the subscales being used for this study show adequate internal consistency ranging from .74 to .85. In this sample, psychological symptoms scales had good reliability at baseline (depression α = .87; anxiety α = .87; and interpersonal sensitivity α = .85; global

symptom severity α =. 91); and at follow-up (depression α = .88; anxiety α = .85; and interpersonal sensitivity α = .83; global symptom severity α = .93).

Sleep problems. This was assessed using the 7-item insomnia severity index (Bastien, Vallières, & Morin, 2001). The ISI is an index of the global severity of insomnia, including perceived daytime consequences and distress. Each item is rated on a 5-point scale from 0 (*not at all*) to 4 (*extremely*), generating a total score that ranges from 0 to 28 (with higher scores indicating more severe insomnia). It has acceptable levels of internal consistency (α = .76 – .78; item-total r = .36 – .67) and concurrent validity (Tang, Wright, & Salkovskis, 2007). In this sample, this measure had excellent reliability (baseline α = .89; follow-up α = .92).

Life satisfaction. This was assessed using the 5-item Satisfaction with Life Questionnaire (SWLS). The 5-item measure assesses satisfaction with life as a whole. For each item, participants rate their satisfaction on a scale from 1 (*strongly disagree*) to 7 (*strongly agree*), generating a total score that ranges from 5 to 35 (with higher sores indicative of more life satisfaction). It shows discriminant validity from emotional well-being measures, good test-retest stability and sufficient sensitivity to detect changes (Pavot & Diener, 1993). In this sample, this measure had good reliability (baseline α = .86; follow-up α = .89).

Stage of change. This was assessed by 9 items from the 32-item Change Assessment Questionnaire (McConnaughy, Prochaska, & Velicer, 1983), which was done to reduce patient burden. Selected items from this questionnaire align with the four stages of change as proposed by Prochaska's transtheoretical stage of change model. Our abbreviated CAQ yields scores on four subscales: precontemplation, which is composed of three items ("The best thing I can do is find a doctor who can figure out how to get rid of my symptoms once and for all"); contemplation, which is composed of three items ("Even if my symptoms don't go away, I am

ready to start changing how I deal with it"); action, which has two items ("I am testing out some stress management techniques to manage my symptoms better"); and maintenance, which has one item ("I use what I have learned to help keep my symptoms under control"). Items are rated on a scale of 0 (*strongly disagree*) to 4 (*strongly agree*). Higher scores on each of the subscales indicate higher levels of that stage of change. In this sample, CAQ had poor reliability at baseline (contemplation α = .61; and action α = .65) and at follow-up (contemplation α = .57; and action α = .77). Reliability for precontemplation was unacceptable both at baseline (α = .31) and follow-up (α = .11).

Statistical Analyses

After data collection, analyses were conducted in SPSS 22.0. The data were screened for missing and out of range values, and frequency distributions of demographic and outcome variables were examined for outliers. Data were also examined for non-normal variables by examining skewness using histograms. Because variables were not highly skewed, only original variables were used in all analyses. Demographic information was analyzed using frequency distributions and measures of central tendency. Internal consistency of the outcome measures was evaluated using Cronbach's alpha measure of reliability.

The success of randomization was determined by comparing the two groups on demographics and baseline levels of the outcome measures, using chi-square and t tests. Attrition analyses compared study completers to those who did not complete the post treatment assessment. An independent-samples t test was used to examine continuous variables. Chi-square analyses (including Fisher's Exact Test) were used to examine categorical variables.

To test for the effects of the intervention versus control condition on outcomes, intent-to-treat (ITT) analyses of the final randomized sample (N = 75) were conducted. ITT analyses were

conducted using a multiple imputation procedure in SPSS 22.0 in which each missing outcome value was replaced with an imputed value, which takes into account the group condition and baseline levels of the outcome measures. Primary analyses of the effects of the interview versus control on the outcome measures were conducted, and within-condition paired t tests were calculated to asses within-condition changes over time. These were followed by a mixed-design (between-within) repeated-measures analyses of variance (RM-ANOVA), assessing between-condition differences from baseline to follow-up. Significant condition x time interactions indicated that the two conditions changed differentially over time. Finally, effect sizes were calculated both within and between conditions. Within each condition, *d* was calculated by subtracting the baseline mean from the follow-up mean and dividing by the standard deviation of that condition's baseline mean. The between-condition effect size ($d_{between}$) was calculated using the following equation: [(Interview follow-up *M* – baseline *M*) – (control follow-up *M* – baseline *M*)] / *SD* of the pooled change scores. A negative *d* within group means that the follow-up score was lower than the baseline score, and a negative *d* between condition effects means that the interview group decreased more than the control group did. All significance tests in this study used a two-tailed *p* value of .05, which notably reduces power given the small sample size.

CHAPTER 4: RESULTS

Preliminary Analyses

Figure 1 demonstrates participant flow through the study. Eighty participants were eligible and interested in participation. These participants were enrolled in the study, completed baseline assessments and were randomized. However, 5 participants were administratively removed from the study for various reasons, including undergoing surgery after randomization (n = 3), drug seeking behavior (n = 1), and criminal charges (n = 1), resulting in a total of 75 randomized participants. One of the removed patients was randomized into the waitlist group, and underwent surgery after randomization, which interfered with follow-up assessment. The other 4 patients were randomized into the interview group; two of them underwent surgery within the 6 weeks and did not schedule an interview; one patient was discovered to have pending criminal charges and medical staff insisted on removing him from the study prior to receiving an interview. Finally, the patient who was thought by the staff to be "seeking drugs" attended 20 minutes of the interview session, and was no longer interested in participating once the goals of the study were reiterated. Hence, these patients were discovered to have not met inclusion criteria.

Baseline Comparisons

T tests and chi-square tests were conducted to ensure the success of randomization between the two groups (Interview, n = 49; Control, n = 26). The two conditions did not differ significantly on age, gender, race, marital status, or education (Table 1) or baseline levels of any outcome measures (Table 3), suggesting that randomization created equivalent groups on these variables. However, there was a statistically significant difference in baseline CAQ maintenance for the two conditions (t (73) = -2.12, p = .038, d = 0.53), such that the mean for CAQ

maintenance for interview group (M = 2.8, SD = 0.9) was greater than that of control group (M = 2.3 years, SD = 1.0). Interview group did not differ significantly from the controls on any of the other outcome measures at baseline.

The majority of participants assigned to the interview group completed the interview, except for 2 participants who did not respond to attempts to schedule an interview nor complete follow-up assessment. Regarding attrition over the follow-up period, of the 75 randomized participants, 8 (10.6%) did not complete follow-up assessments, and were considered "non-completers" (Interview, n = 6, including the two who did not do the interview; Control, n = 2). Completers were defined as those who completed the follow-up assessment at 6 weeks. Completers and noncompleters did not differ significantly on most demographic and baseline levels of the outcome measures (Table 2). A significant difference was found for baseline BSI anxiety (t (73) = -4.43, p < .001, d = 0.97), with completers (M = 1.3, SD = 1.0) having significantly higher anxiety than non-completers (M = 0.6, SD = 0.3) at baseline. There was also a significant difference between completers and non-completers on SIQ psychological attributions (t (73) = -1.99, p = .04, d = 0.85), with completers (M = 1.2, SD = 0.7) more likely to endorse psychological attributions for their symptoms than non-completers (M = 0.8, SD = 0.4) at baseline.

Figure 2. Flow Chart of Participants through the Study

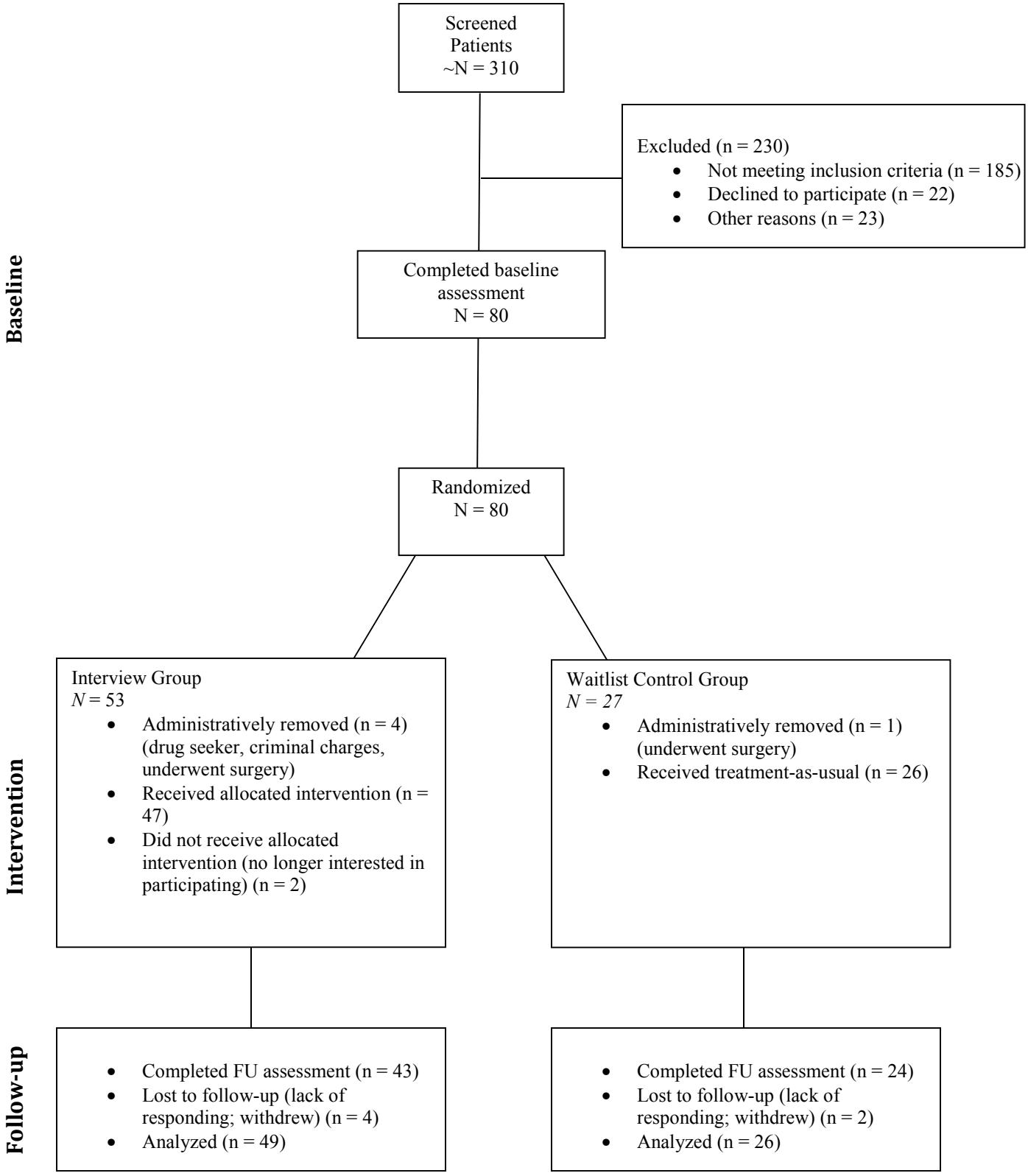


Table 1

Comparison of Conditions on Demographic Measures at Baseline

		Total Sample ($N = 75$)	Interview ($n = 49$)	Control Group ($n = 26$)	t/χ^2	p
Age (years)	*M (SD)*	39.2 (13.7)	39.1 (13.7)	39.2 (13.8)	0.03	.97
Years of Education	*M (SD)*	14.0 (1.9)	14.08 (2.0)	13.96 (1.6)	-0.27	.79
Gender					0.11	.74
Men	*n* (%)	10 (13.3)	7 (14.3)	3 (11.5)		
Women	*n* (%)	65 (86.7)	42 (85.7)	23 (88.5)		
Ethnicity					0.42	.52
European American	*n* (%)	59 (78.7)	37 (75.5)	22 (84.6)		
African American	*n* (%)	12 (16.0)	9 (18.4)	3 (11.6)		
Relationship Status					2.15	.14
Partnered	*n* (%)	29 (38.7)	16 (32.7)	13 (50.0)		
Other	*n* (%)	46 (61.3)	33 (67.3)	13 (50.0)		

Note. All tests were two-tailed.

Chi-square analysis for ethnicity compared European American to African American, due to the small numbers in the Other category ($n = 4$). Chi-square analysis for marital status was analyzed comparing Partnered (married or living together with a significant other) to Other (single, separated, divorced, widowed), due to the small numbers in the other cells.

Table 2.

Participants Who Completed the Follow-up Assessments Compared to Participants Who Were Lost to Follow-up on Demographic and Baseline Levels of the Outcome Measures

	Completers (n = 67)	Non-Completers (n = 8)	t/χ^2	p	d/phi
Age (years) *M (SD)*	38.9 (13.8)	41.4 (13.4)	0.48	.63	-0.18
Education (years) *M (SD)*	14.1 (1.8)	13.5 (1.9)	-0.88	.38	0.32
Somatic Symptoms *M (SD)*	12.04 (3.39)	13.13 (5.96)	0.78	.44	-0.22
Pain Severity *M (SD)*	4.90 (2.16)	4.69 (2.51)	-2.62	.79	0.09
Pain Interference *M (SD)*	4.96 (2.64)	5.21 (3.17)	0.24	.81	-0.08
Depression *M (SD)*	1.22 (0.94)	1.23 (0.89)	0.02	.98	-0.01
Anxiety *M (SD)*	1.33 (1.01)	0.60 (0.31)	-4.43	<.01	0.97
Interpersonal Sensitivity *M (SD)*	1.37 (1.15)	1.38 (0.09)	0.02	.98	-0.01
Symptom Severity *M (SD)*	1.30 (0.85)	1.03 (0.60)	-0.86	.39	0.45
Insomnia Severity *M (SD)*	16.21 (6.39)	13.13 (7.68)	-1.26	.21	0.44
SIQ Psychological *M (SD)*	1.24 (0.67)	0.76 (0.44)	-1.99	.04	0.85
SIQ Somatic *M (SD)*	1.01 (0.62)	0.91 (0.43)	-0.43	.67	0.19
SIQ Environmental *M (SD)*	1.33 (0.55)	1.03 (0.28)	-1.52	.13	0.68
Life Satisfaction *M (SD)*	3.34 (1.46)	2.55 (1.30)	-1.46	.15	0.57
CAQ Pre-contemplation *M (SD)*	2.11 (0.65)	1.63 (0.88)	-1.91	.06	0.62
CAQ Contemplation *M (SD)*	3.04 (0.69)	2.58 (0.68)	-1.79	.08	0.67
CAQ Action *M (SD)*	2.29 (0.95)	2.12 (1.09)	-0.46	.65	0.17
CAQ Maintenance *M (SD)*	2.64 (1.01)	2.88 (0.64)	0.64	.53	-0.28

Note. All tests were two-tailed.

Chi-square analysis for marital status was analyzed comparing only Partnered (married or living together with a significant other) to Other (single, separated, divorced, widowed), due to the small numbers in the other cells.

Primary Analyses

The outcome data for each condition are presented in Table 3; specifically, means and standard deviations for each score at baseline and the 6-week follow-up assessment. Regarding the primary outcome measure reflecting change in somatic symptoms (assessed with the PHQ-15), the interview condition had a significant reduction in symptoms from baseline to follow-up, showing medium effect size (p = .002, d = -0.49), whereas the control condition showed no significant change and a small effect (d = -0.21) over time. However, the conditions did not differ significantly in their changes over time (F (1, 73) = 1.69, p = .20, d = -0.32). Regarding the primary outcome measures reflecting change in attributions about the role of psychological factors in patients' symptoms, the two conditions did not differ on any of the three symptom attributions (measured by SIQ subscales) from baseline to follow-up. Indeed, neither condition alone showed a significant change over time on any of the three attributions.

Changes in pain severity and interference (BPI) were also assessed. The interview group experienced reductions in pain severity from baseline to follow-up (p < .001, d = -0.38), whereas the control condition showed a small and nonsignificant change (d = .03) over time. There was a significant difference between groups on changes in pain severity (F (1, 73) = 6.57, p = .01, d = -0.67). The interview group also experienced reductions in pain interference from baseline to follow-up (p = .001, d = -0.42), whereas the control condition showed small and nonsignificant change (d = .19) over time. There was a significant difference between groups on change in pain interference over time (F (1, 73) = 10.74, p = .002, d = -0.75). As for insomnia severity (ISI), the interview group experienced a decrease in sleep problems from baseline to follow-up (p = .002, d = -0.41), whereas the control condition showed no significant change and a small effect (d =

0.16) over time. There was a significant difference between the groups on change in sleep problems over time (F (1, 73) = 11.10, p = .001, d = -0.75).

Participants in the interview group improved on some psychological symptoms relative to controls from baseline to follow-up. The interview group experienced a reduction in psychological symptoms (p = < .001, d = -0.52), whereas the control condition showed no change and a minimal effect (d = 0.01) over time. There was a significant difference between the groups on changes in *psychological symptoms* over time (F (1, 73) = 6.56, p = .01, d = -0.60). Specifically, the interview group experienced a reduction in BSI Depression (p = .001, d = -0.43), whereas the control condition showed no change and a small effect (d = 0.05) over time. There was a significant difference between the groups on changes in depression scores over time (F (1, 73) = 4.93, p = .03, d = -0.51). Changes in BSI Interpersonal Sensitivity were similar. Again, the interview group experienced a reduction in interpersonal sensitivity (p = .001, d = -0.45), whereas the control condition showed no change and a small effect (d = 0.07) over time. There was a significant difference between the groups on changes in interpersonal sensitivity over time (F (1, 73) = 6.05, p = .02, d = -0.57). Finally, the interview group had a significant reduction in BSI Anxiety from baseline to follow-up (p = .001, d = -0.39), whereas the control condition showed no change and a small effect (d = -0.09) over time. However, the conditions did not differ significantly in their reduction in anxiety over time (F (1, 73) = 2.50, p = .12, d = -0.39). Finally, the two conditions did not differ on changes in life satisfaction (SWLS) from baseline to follow-up.

Analyses of patients' motivation for change, as assessed by CAQ, showed a significant decrease in CAQ Contemplation scores in the interview condition (p < .01, d = -0.58), whereas the control condition showed no significant change and a small effect (d = 0.22) over time. The

conditions differed significantly in their change on contemplation scores over time (F (1, 73) = 9.03, p = .004, d = -0.67). As expected, the interview group showed a significant decrease in CAQ Precontemplation scores (p = .02, d = -0.31) and a significant increase in CAQ Action scores (p = .001, d = 0.45) from baseline to follow-up, whereas the controls showed no change and a small effect on these variables (d = -0.20 and 0.19; respectively) over time. However, contrary to expectations, the two groups did not differ significantly in their change over time on precontemplation (F (1, 73) = 0.34, p = .56, d = -0.15) or action scores (F (1, 73) = 1.24, p = .28, d = 0.16). Given the low reliability of these scales, the results should be interpreted with caution and replicated with the full scale.

Ancillary Analyses

Data were further explored in a number of ways, using different modes of analyses and different subsets of the sample. As an alternative method to RM ANOVA for analyzing the data, analyses of covariance were conducted to compare the two conditions on all outcome measures (physical symptoms, psychological symptoms, and changes in attributions and motivation) while controlling for baseline levels of the outcome measure. The results of these analyses are presented in Table 4. This analysis yielded similar results to RM ANOVAs. For instance, pain severity, pain interference, interpersonal sensitivity, depression, psychological symptom severity, insomnia severity, and CAQ contemplation all remained significantly different between interview group and waitlist control group at the 6-week follow-up (p < .05). Anxiety scores (p = .009) and CAQ action scores (p = .04) became significantly different between conditions, with participants in the interview group demonstrating lower anxiety and higher action scores than those in the waitlist group at the 6-week follow-up. As in the initial analyses, the remaining outcome measures did not significantly differ between conditions.

Second, intent-to-treat analyses were conducted using the baseline value carried forward to replace missing values, which assumes no change from baseline, rather than using a multiple imputation procedure in which each missing outcome value was replaced with an imputed value calculated using a multiple imputation procedure in SPSS 22.0. This analysis did not alter the significant findings from the primary analyses noted above, conducted with RM ANOVA, except for depression and interpersonal sensitivity, which became nonsignificant at the 6-week follow-up, p = .08 (partial eta^2 = 0.07) and p = .06 (partial eta^2 = 0.08), respectively. Third, RM ANOVAs were conducted only on the sample of 67 completers (Interview n = 43; Control n = 24; Total sample N = 67), and results did not differ from analyzing the results with the Total sample (N = 75) described above (with the multiple imputation technique).

Table 3.

Within and Between-Condition Comparisons of Outcomes from Baseline to 6-week Follow-up

Outcome Measure	Interview Condition (n = 49)		Waitlist Condition (n = 26)		Condition x Time Interaction		
	M (SD)	d_{within}	*M (SD)*	d_{within}	*F* (1,73)	*p*	$d_{between}$
Somatic Symptoms							
Baseline	12.18 (3.88)		12.19 (3.45)				
6 weeks	10.28 (5.30)		11.48 (3.58)				
Change Score	-1.89 (4.13)	-0.49**	-0.71 (2.89)	-0.21	1.69	.20	-0.32
SIQ Psychological							
Baseline	1.15 (0.61)		1.27 (0.75)				
6 weeks	1.05 (0.72)		1.28 (0.58)				
Change Score	-0.09 (0.74)	-0.16	0.01 (0.49)	0.01	0.67	.42	-0.20
SIQ Somatic							
Baseline	0.97 (0.58)		1.06 (0.64)				
6 weeks	0.91 (0.51)		1.02 (0.48)				
Change Score	-0.06 (0.49)	-0.10	-0.04 (0.45)	-0.06	0.03	.86	-0.04
SIQ Environmental							
Baseline	1.26 (0.54)		1.37 (0.54)				
6 weeks	1.23 (0.51)		1.38 (0.63)				
Change Score	-0.03 (0.54)	-0.06	0.01 (0.52)	0.02	0.11	.74	-0.08
Pain Severity							
Baseline	4.91 (2.17)		4.83 (2.24)				
6 weeks	4.08 (2.45)		4.88 (1.90)				
Change Score	-0.83 (1.26)	-0.38***	0.04 (1.29)	0.03	6.57	.01	-0.67
Pain Interference							
Baseline	5.23 (2.81)		4.55 (2.39)				
6 weeks	4.05 (2.94)		5.01 (2.81)				
Change Score	-1.18 (2.25)	-0.42**	0.45 (1.63)	0.19	10.74	.002	-0.75
Sleep Problems							
Baseline	16.04 (5.95)		15.58 (7.69)				
6 weeks	13.62 (7.57)		16.81 (6.82)				
Change Score	-2.42 (5.08)	-0.41**	1.23 (3.20)	0.16	11.09	.001	-0.75
Depressive Symptoms							
Baseline	1.26 (0.90)		1.15 (0.99)				
6 weeks	0.86 (0.92)		1.19 (0.82)				
Change Score	-0.41 (0.79)	-0.43**	0.05 (0.95)	0.05	4.93	.03	-0.51
Anxiety Symptoms							
Baseline	1.18 (1.01)		1.40 (0.94)				
6 weeks	0.79 (0.82)		1.31 (0.77)				
Change Score	-0.38 (0.76)	-0.39**	-0.09 (0.74)	-0.09	2.50	.12	-0.39

Interpersonal Sensitivity							
Baseline	1.42 (1.12)		1.26 (1.16)				
6 weeks	0.92 (0.96)		1.34 (0.92)				
Change Score	-0.50 (0.99)	-0.45**	0.09 (0.95)	0.07	6.05	.02	-0.57
Psychological Symptoms							
Baseline	1.27 (0.83)		1.27 (0.85)				
6 weeks	0.84 (0.82)		1.28 (0.69)				
Change Score	-0.43 (0.68)	-0.52***	0.01 (0.75)	0.01	6.56	.01	-0.60
Life Satisfaction							
Baseline	3.21 (1.45)		3.34 (1.49)				
6 weeks	3.51 (1.57)		3.39 (1.37)				
Change Score	0.29 (1.16)	0.21	0.05 (0.96)	0.03	0.88	.35	0.22
CAQ Pre-contemplation							
Baseline	2.03 (0.71)		2.10 (0.65)				
6 weeks	1.81 (0.61)		1.97 (0.53)				
Change Score	-0.22 (0.64)	-0.31*	-0.13 (0.58)	-0.20	0.34	.56	-0.15
CAQ Contemplation							
Baseline	3.07 (0.71)		2.85 (0.67)				
6 weeks	2.66 (0.68)		3.00 (0.68)				
Change Score	-0.41 (0.86)	-0.58**	0.16 (0.62)	0.22	9.03	.004	-0.67
CAQ Action							
Baseline	2.32(0.98)		2.19 (0.96)				
6 weeks	2.76 (0.77)		2.37 (0.78)				
Change Score	0.45 (0.95)	0.45**	0.18 (1.04)	0.19	1.24	.27	0.28
CAQ Maintenance							
Baseline	2.84 (0.94)		2.35 (0.96)				
6 weeks	2.81 (0.83)		2.49 (0.95)				
Change Score	-0.02 (1.07)	-0.03	0.14 (1.04)	0.14	0.43	.51	-0.15

d-within is the within-condition effect size ((post M – baseline M) / baseline SD).
d-between is the between-condition effect size ((Interview follow-up *M* – baseline *M*) – (control follow-up *M* – baseline *M*)) / *SD* of the pooled change scores.
* $p < .05$, ** $p < .01$, *** $p < .001$ (two-tailed paired-samples t test within each group)

Table 4.

Results of Analyses of Covariance at Baseline and Follow-up, comparing Condition Group Adjusted Means, Covarying for Baseline Values of Outcomes

Outcome Measure	Time Point	Interview Group (n = 49)	Control Group (n = 26)	$F(df)$	p	Partial Eta-squared
Physical Symptoms	Baseline M (SD)	12.18 (3.88)	12.19 (3.45)			
	6-week M (SD)	10.28 (5.30)	11.48 (3.58)			
	6-wk Adj. M (SE)	10.29 (0.53)	11.47 (0.73)	1.74	0.19	0.02
SIQ Psychological	Baseline M (SD)	1.15 (0.61)	1.27 (0.75)			
	6-week M (SD)	1.05 (0.72)	1.28 (0.58)			
	6-wk Adj. M (SE)	1.08 (0.07)	1.23 (0.10)	1.39	.24	0.02
SIQ Somatic	Baseline M (SD)	0.97 (0.58)	1.06 (0.64)			
	6-week M (SD)	0.91 (0.51)	1.02 (0.48)			
	6-wk Adj. M (SE)	0.93 (0.05)	0.98 (0.07)	0.45	.51	0.01
SIQ Environmental	Baseline M (SD)	1.26 (0.54)	1.37 (0.54)			
	6-week M (SD)	1.23 (0.51)	1.38 (0.63)			
	6-wk Adj. M (SE)	1.25 (0.07)	1.34 (0.09)	0.65	.42	0.01
Pain Severity	Baseline M (SD)	4.91 (2.17)	4.82 (2.24)			
	6-week M (SD)	4.08 (2.45)	4.88 (1.90)			
	6-wk Adj. M (SE)	4.06 (0.18)	4.83 (0.25)	6.61	0.01	0.08
Pain Interference	Baseline M (SD)	5.23 (2.81)	4.55 (2.39)			
	6-week M (SD)	4.05 (2.94)	5.01 (2.81)			
	6-wk Adj. M (SE)	3.86 (0.28)	5.36 (0.39)	9.42	.003	0.12
Sleep Problems	Baseline M (SD)	16.04 (5.95)	15.58 (7.69)			
	6-week M (SD)	13.62 (7.57)	16.81 (6.82)			
	6-wk Adj. M (SE)	13.48 (0.64)	17.08 (0.88)	10.93	.001	0.132
Depression	Baseline M (SD)	1.26 (0.90)	1.15 (0.99)			
	6-week M (SD)	0.86 (0.92)	1.19 (0.82)			
	6-wk Adj. M (SE)	0.83 (0.11)	1.24 (0.14)	5.11	.03	0.07
Anxiety	Baseline M (SD)	1.18 (1.01)	1.40 (0.94)			
	6-week M (SD)	0.79 (0.82)	1.31 (0.77)			
	6-wk Adj. M (SE)	0.83 (0.08)	1.23 (0.12)	7.11	.009	0.09
Interpersonal sensitivity	Baseline M (SD)	1.42 (1.12)	1.26 (1.16)			
	6-week M (SD)	0.92 (0.96)	1.34 (0.92)			
	6-wk Adj. M (SE)	0.89 (0.11)	1.39 (0.15)	6.87	.01	0.08
Psychological Symptoms	Baseline M (SD)	1.27 (0.83)	1.27 (0.85)			
	6-week M (SD)	0.84 (0.82)	1.28 (0.69)			
	6-wk Adj. M (SE)	0.84 (0.09)	1.28 (0.12)	8.68	.004	0.11
Life Satisfaction	Baseline M (SD)	3.21 (1.45)	3.34 (1.49)			
	6-week M (SD)	3.51 (1.57)	3.39 (1.37)			
	6-wk Adj. M (SE)	3.54 (0.15)	3.23 (0.20)	0.75	.39	0.01

CAQ Pre-contemplation	Baseline M (SD)	2.03 (0.71)	2.10 (0.65)			
	6-week M (SD)	1.81 (0.61)	1.97 (0.53)			
	6-wk Adj. M (SE)	1.82 (0.07)	1.95 (0.09)	1.08	.30	0.02
CAQ Contemplation	Baseline M (SD)	3.07 (0.71)	2.85 (0.67)			
	6-week M (SD)	2.66 (0.68)	3.00 (0.68)			
	6-wk Adj. M (SE)	2.63 (0.09)	3.06 (0.13)	7.14	.009	0.09
CAQ Action	Baseline M (SD)	2.32(0.98)	2.19 (0.96)			
	6-week M (SD)	2.76 (0.77)	2.37 (0.78)			
	6-wk Adj. M (SE)	2.75 (0.10)	2.39 (0.14)	4.08	.04	0.05
CAQ Maintenance	Baseline M (SD)	2.84 (0.94)	2.35 (0.96)			
	6-week M (SD)	2.81 (0.83)	2.49 (0.95)			
	6-wk Adj. M (SE)	2.76 (0.12)	2.59 (0.17)	0.73	.39	0.01

Note. All tests were two-tailed.

CHAPTER 5: DISCUSSION

In this study, the 90-min interview session sought to help patients identify and endorse links between their emotional stress and their physical symptoms. It also sought to engage patients in an exercise to enhance emotional awareness, experiencing, and expression, with the goal of reducing their physical symptoms and psychological distress. Although the first goals may not have been achieved, the second was.

This trial has several key findings. First, the interview was effective in reducing pain severity, pain interference, depression, interpersonal sensitivity, and psychological symptoms, in addition to improving sleep problems after 6 weeks, compared to standard care without the interview, among primary care patients with medically unexplained symptoms. This finding suggests that an emotional processing approach has the potential to be a viable technique for targeting pain and psychological symptoms among patients with medically unexplained symptoms. The finding that the interview led to significantly greater reductions in pain severity and interference after 6 weeks, compared to controls, is notable, because it suggests that that emotional awareness and expression training is effective in reducing pain, which is considered the hallmark of medically unexplained syndromes. It may be that a technique that helps people confront rather than avoid emotionally laden experiences, better targets core factors (e.g., emotional avoidance, failure to process and resolve stress) that are responsible for maintaining and prolonging stress-related symptoms. This interpretation is in line with research that has demonstrated a relationship between stressful life events and pain symptom exacerbation (Abbass et al., 2009; Burger et al., 2016; Hsu et al., 2010; Lampe et al., 2003; Slavin-Spenny et al., 2013).

Second, the interview was effective at improving depression, interpersonal sensitivity, and general psychological symptom severity from baseline to 6-week follow-up, as compared to the waitlist control. Similarly, the interview was also effective at improving sleep problems from baseline to follow-up. Our experiential exercise is thought to target avoidance of negative emotional experiences and facilitate the processing of unresolved stress. Previous research has shown that emotional expression can directly target psychological symptoms by helping to regulate internal states (Ekman & Davidson, 1993), which is associated with reduced interpersonal sensitivity and increased prosocial behavior (Lopes, Salovey, Côté, Beers, & Petty, 2005) as people are more able to make balanced appraisals of their environment. This pattern of findings is aligned with research suggesting that treatments that target pain patients' emotional complexity can influence social information processing as well (Davis, Zautra, & Smith, 2004). As such, an approach that enhances emotional skills may increase the ability of those with chronic pain conditions to preserve positive engagement during their experience of pain (Zautra, 2006).

In addition, in terms of motivation for change, the interview had an effect on contemplation thinking, but no effect between the two groups on precontemplative and action-oriented thinking. However, patients in the interview group reported reductions in precontemplative and contemplative thinking, and a significant increase in action oriented perspectives from baseline to follow-up. Decreases in precontemplation and contemplation thoughts about readiness for change are congruent with expected effects of the intervention, because it suggests that patients are no longer “wondering” about their readiness to change and might have already initiated the change process. In addition, increases in action thinking are also aligned with expectations as patients are shifting toward a new approach for managing their

condition. It is likely that patients entered the study contemplating change, between precontemplation and contemplation, and shifted toward action-based perspectives 6 weeks later, as reflected by increases in action scores.

Third, although the interview did not affect somatic symptoms, patients in the interview group experienced significant reductions with a medium effect in somatic symptoms over time, whereas the control group had a meaningfully smaller effect. It is notable that PHQ-15 was used both as a screening and change measure in this study, even though PHQ-15 has been developed and validated as a screening tool (Kroenke et al., 2002). Other investigations by the developers ascertained the PHQ-15 as a well-validated measure for detecting and monitoring somatization (Kroenke et al., 2010) with no mention of its use as an outcome measure. More importantly, in an intervention study for MUS, researchers have used PHQ-15 to determine symptom severity at baseline, but their primary measure of change was Clinical Global Impression (CGI) rating of severity of physical symptoms (CGI-severity) and the CGI rating of improvement of physical symptoms (CGI-improvement) (Escobar et al., 2007), following methods done by Allen and colleagues (Allen, Woolfolk, Escobar, Gara, & Hamer, 2006). Hence, it appears that PHQ-15 is a well-validated screening tool, and similar to other general physical symptom checklists, it may not reflect change very well. Finally, the CAQ subscales and PHQ-15 had low reliability, which likely affected their validity as a change measures.

Contrary to expectations, there were no changes on primary measures of change in symptom attributions about the role of psychological factors in patients' symptoms. These findings were surprising, as the intervention purported to raise the patient's awareness about the role of stress and emotional factors in the manifestation and exacerbation of their physical symptoms. It is notable that the SIQ has not been tested for its use as a change measure, and it is

possible that attributions assessed by it are not readily changed. Other studies of SIQ have not used it as a change measure, and generally categorize participants based on their attributional style into psychologisers, somatisers, and normalisers. For example, one study of Gulf War veterans demonstrated associations between these three attributional styles and patterns of symptom reporting, and found that psychologising was associated with higher symptom reporting, whereas somatisers and mixed-attribution also demonstrated higher reporting than normalisers (Wright, McFarlane, Clarke, Sim, & Kelsall, 2015). Research has also tested the ability of attributional styles to predict psychiatric conditions, namely depression and anxiety (Kessler, Heath, Lloyd, Lewis, & Gray, 1999), suggesting that the SIQ may be tapping into more stable trait-like constructs that are associated with symptom endorsement and psychological functioning. Research also shows distinguishable attributional patterns between patients with somatoform disorder and those with chronic pain (Hiller et al., 2010), and perhaps the heterogeneous nature of our sample made it difficult to identify distinct attributional patterns and changes over time. In addition, perhaps attributional styles should have been conceptualized as distinct predictors of change in symptom endorsement instead of mutable attitudes.

In addition, given the complexity of medically unexplained syndromes, the patients might have had a more comprehensive or multi-causal understanding of their symptoms. For instance, patients with chronic headaches may recognize the role of psychological variables in initiating or maintaining their headaches, but also believe that organic causes underlie their vulnerability to developing headaches, and environmental factors (e.g., light) can exacerbate their symptoms. Finally, given the sample's range of health problems, some of the conditions may have had a more primary organic cause versus conditions that may be more stress-driven. For example, research shows that headaches have a neurological basis, and they are likely

initiated by one of numerous pathways including nerve stimulation, irritation or disinhibition (Bogduk et al., 2000). This might influence patients' attributions regarding the etiology of their conditions, and render it rather challenging to reliably assess changes in attributions across a wide range of conditions of complex etiology and diverse presentation.

Finally, the groups did not differ on life satisfaction over time. It is possible that emotional awareness and expression training may be an effective approach for reducing negative emotions and accompanying physical symptoms, but not as effective at improving overall positive affective states like life satisfaction. The null findings on the life satisfaction measure may be due to a number of factors. Improving life satisfaction may take longer, require a larger improvement in psychological functioning, or require an intervention designed to enhance satisfaction, which is conceptually different from targeting affect. The SWLS scale assesses *global* life satisfaction, which by definition is not circumscribed to one domain such as physical health, and hence it might not be affected by change in that domain. Research on the relationship between cognitive-judgmental aspect of subjective well-being (life satisfaction) and hedonic balance (affectivity) is mixed. Some studies show a relationship between improved depression and improved quality of life (Ruo et al., 2003), whereas other studies suggest that among recovering depressed patients, quality of life remains lower than that among non-depressed patients (Dan & Younossi, 2010). Hence, it is possible that improving psychological functioning does not majorly affect the global appraisal of a person's life, which includes family, job, achievements, and other joys and regrets.

Clinical observations of the interviewers support study findings, and suggest that the interview session was an effective and important experience for study participants. Although formal content analyses were not conducted, some interview observations are noted in this

section. On average, interview sessions lasted for 90 minutes (*SD* = 6.8), and ranged in content, depending on the nature of patients' trauma and conflict. For example, some patients identified sexual abuse or rape experiences as their stressful event, whereas others identified relational conflict, such as strained relationships with parents and sibling, or marital conflict, as their primary stressor. Interview sessions also ranged in intensity and resulted in variable patient responses. This variability was related to several factors, including patients' level of engagement and the nature of their conflict. For example, some patients became fully engaged and expressed intense emotion (e.g., anger) toward perpetrators and enacted adaptive aggression that had been suppressed. Other patients experienced difficulty identifying and expressing emotion, and the emotional awareness and expression components were new to them, whereas others expressed previously avoided emotions (e.g., expressing love or need for a parent with whom they are in conflict). The session served as a novel opportunity to disclose stressful experiences, become aware of emotions, and express emotions that may have been previously avoided.

Overall, patients expressed a range of positive reactions to the interview, including newfound awareness, surprise, appreciation, and relief. Many patients appreciated learning about the links between their stress and physical symptoms, and for a subset of patients, this was a new and "eye-opening" model of understanding their symptoms. Patients also noted that they were surprised by their emotional experience and did not realize they were holding on to certain emotions, as one patient noted that she "did not realize [she] was harboring all this anger" toward her neglectful father. Most patients felt validated by this experience, and noted both in session and at the 6-week follow-up that the therapists were validating and sensitive to their experiences. Many patients experienced intense emotions during the experiential exercise, but often times expressed relief at the end of the exercise. For example, one patient expressed anger and then

sympathy toward her mother, who intimidates her badly. The patient expressed excitement about the relief that she felt during the interview and the reduction in her symptoms. The symptom relief following the experiential session was a pivotal moment that the therapists highlighted to patients to illustrate the immediate effects of expressing previously avoided and important emotion.

Finally, follow-up qualitative reports by patients showed that patients were appreciative of the interview experience. Patients noted changes in their understanding of their symptoms. For example, one patient wrote, "glad to now understand how much my emotional stress triggers my painful symptoms, it happened before our eyes during the interview after I cried so that opened my eyes up to things. Need to work on getting over past. Only negative thing wish I had more time!" Similarly, another participant concluded, "I realized a lot of physical pain can be linked to how you are feeling emotionally. In order for some of the physical pain to go away you have to resolve the emotional problems. When I met with the interviewer she brought up events in my life I needed to deal with it and I have. I feel a lot better emotionally and physically." Patients also expressed a need to seek mental health services. For example, "I believe I need more intense mental health care." Others patients noted learning more about themselves and their personality attributes; for example, "I learned I am good at anger and not communication."

Study Strengths and Limitations

This study has many strengths and a number of limitations. First, participant attrition was fairly low and intervention sessions were well attended, as only two participants randomized to the interview group did not schedule an interview. In addition, participants were followed 6 weeks post-randomization so benefits could be assessed over time. It is also important to note that participants were recruited from primary care and not a tertiary specialty clinic. This means

that the sample consists of patients who are not typically engaged in psychotherapy and have likely not disclosed or processed the issues that they are bringing. Patients in psychological care, and often in special medical care, have heightened distress and perhaps more experience with mental health providers, possibly leaving them less likely to respond positively to this intervention. In addition, the current sample is likely quite generalizable, given the high prevalence of these conditions in primary care. This sample likely represents the wide range of people who are characterized as having medically unexplained symptoms in the community, given that some are treatment seeking for their symptoms, and others were seeking treatment for other reasons and simply met criteria on our screening measure.

Another strength of this study is the range of measures, which captured physical and psychological symptoms, in addition to changes in attributions about the role of psychological factors in patients' symptoms and motivations for change. However, data were primarily collected by self-report, which can be problematic. Participants may not be able to accurately recall their experiences over time, which may have biased these findings. Participants may try to respond favorably, in which case social desirability may have biased our findings. Other types of assessments (e.g., symptom diaries, physician-rated measures, biological measures) can provide more accurate or objective information. Another strength of this study is that it used a comparison waitlist control condition, which controlled for many threats of internal validity (e.g., maturation, history, statistical regression to the mean). However, a waitlist did not control for nonspecific aspects of the interview (e.g., attention, support). A credible placebo control (e.g., relaxation training) would have helped to determine whether or not nonspecific factors influenced treatment outcomes.

Some study limitations include a highly heterogeneous study sample, recruited via

different methods (i.e., some were recruited in the waiting room by research staff, or a referral by a physician or a clinic psychologist). Referrals by a clinic psychologist may have contributed to sampling bias, however, only a small percentage of the patients were recruited by this method. In addition, the relevance of effects to treatment-seeking patients versus non-treatment seeking individuals could not be determined. An important limitation is a limited statistical power due to a modest sample size and the imbalanced cell size in the two conditions, which was adopted to maximize interview patients for secondary analyses. The low power limits the ability to interpret null findings, but in this sample the groups provided sufficient power to detect medium effects but were underpowered to detect meaningful changes in the small-to-medium range. The sample also included many more women (87%) than men. Although the distribution reflects the population of medically unexplained conditions in general (Nimnuan, Hotopf, & Wessely, 2001) and of those in primary care specifically, these findings will not necessarily generalize to men with these symptoms/conditions. It is notable that the study did not have sufficiently-sized subgroups to explore potential differences between European American and African American participants. Only 4 participants belonged to other racial groups, which further limits generalizability of findings. Research exploring health and emotion across race has shown different patterns of psychopathology, including comparative rates of anxiety disorders (Brown, Shear, Schulberg, & Madonia, 1999), and different depressive responses (Blazer, Landerman, Hays, Simonsick, & Saunders, 1998; Decoster, 2003). This suggests that African Americans may have different emotional response patterns that would be important to study.

Next, some of the study measures had poor reliability in this sample. For example, the PHQ-15 had poor internal consistency at baseline, but good internal consistency at the 6-week follow-up. The poor value seen at baseline is much lower than previous studies, which have

reported at least acceptable internal consistency (e.g., α *range* = 0.79- 0.89) (Interian, Allen, Gara, Escobar, & Díaz-Martínez, 2006; Kroenke et al., 2002). It is also unclear why internal consistency was lower at baseline and increased over time. Possible explanations may include the heterogeneity of the sample, and patients may have not endorsed items consistently due to the varying nature of their conditions and their pain experience, suggesting that lower consistency values can be expected given the diversity of constructs measured. Alternatively, patients may have provided more thoughtful and consistent responses after participating in the interview, resulting in improved reliability. In addition, in this study, we did not use the original CAQ measure and selected 9 relevant items to reduce patient burn, which likely led to the unacceptable to poor baseline reliability (α *range*= .31 - .65), and unacceptable to acceptable follow-up reliability (α *range* = .11 - .77). This low reliability is likely due to a number of factors, including a small and inconsistent number of items on the subscales. For example, CAQ maintenance was made of one item "I use what I have learned to help keep my symptoms under control", limiting its validity and reliability in measuring what it purports to measure. Future studies should use the complete 32-item CAQ measure with established validity and reliability (CAQ; McConnaughy, Prochaska, & Velicer, 1983).

Finally, treatment fidelity, defined as the strategies that monitor and enhance the accuracy and consistency of an intervention, was not formally assessed. However, to offset this limitation, interviews were audio recorded, and some were listened to for supervisory purposes. Also, there was a learning curve for therapists, given the complexity of the interview, which involved various domains (e.g. medical history, stress history, emotional processing and experiencing), and required some degree of flexibility to tailor it to the individual needs of each participant. However, both therapists received weekly supervision by a licensed clinical psychologist who

has expertise in stress, emotional processes, and emotional exposure approaches to intervention. Supervision was group-based and involved didactics, a review of audiotaped samples, and extensive feedback. All of these efforts likely improved knowledge, competence, and adherence of the therapists.

Clinical observations shed some light into study limitations. Overall, patients' engagement in the interview varied. Individual differences may account for the level of patients' engagement in the intervention, and hence the expected benefit. It appears that for a subset of patients who were unaware of avoided emotional experiences, satisfied with their current relationships, or otherwise not motivated for change, they appeared to have the least success with the interview. It is also important to note that a minority of patients lacked insight or did not understand the treatment rationale, and hence had difficulty engaging with the interview. In addition, some participants who generally had an avoidant style tended to deny any emotional conflict and had difficulty with the emotional experiencing exercises. For example, one participant endorsed childhood physical and emotional abuse by his parents but did not acknowledge that he might currently have conflicted feelings toward his parents that he wants to process, "it's all behind me," he explained. Others commented that it was hard to reconnect with their buried anger and found the session exercise challenging; "I'm not angry now, and it's hard for me to pretend that I am." Clinical observations suggest that a subset of patients found the interview unconventional, and often times noted that it was not what they were expecting. More research is needed to determine what patient characteristics are associated with patient outcomes for this population, and how to best target these in treatment.

Clinical implications

The study has important clinical implications. First, it demonstrates the feasibility of implementing this interview in a primary care setting with patients who have medically unexplained conditions. Second, study results show that one interview session is effective in helping patients reduce their physical symptoms and improve their psychological functioning, with no evidence of harmful effects. Third, the study demonstrates how current medical practices are missing this entire realm of psychological functioning and contributors to poor health, which needs attention. It appears that a single emotional awareness and expression interview, conducted in the primary care setting, is a viable technique to improve symptoms, as well as shift readiness and motivation for seeking psychologically-oriented treatment.

In addition, research on psychological interventions for medically unexplained symptoms has focused primarily on cognitive and behavioral approaches to intervention (Nezu, Nezu, & Lombardo, 2001), and more recently, mindfulness-based cognitive therapy (Van Ravesteijn et al., 2014) which seek to *decrease* arousal and manage symptoms. This is the first study to systematically assess a brief one-session intervention targeting emotional awareness and expression for primary care patients with medically unexplained symptoms, and the study has encouraging results. Thus, an emotion-focused approach may be a useful technique for people with MUS for a number of reasons. First, it is brief, requiring participants to attend as little as one session. Next, it is effective in reducing pain symptoms, which is a hallmark of MUS. It also teaches patients to experience and express emotions, which has the potential to not only improve health and functioning, but also is likely to enhance interpersonal communication and help individuals to develop and maintain more meaningful relationships.

<u>Future Directions</u>

It is important to replicate this study using a larger sample that is informed by a power analysis to ensure reliability of the findings. Such a study should also include additional health outcomes that may be affected by these interventions. For example, one might include measures examining assertiveness levels, interpersonal functioning, and healthcare utilization. It is also unclear exactly how emotional awareness and expression training operates relative to cognitive-behavioral approaches. In order to enhance understanding of the active ingredients of change, process research examining potential mediators (e.g., self-efficacy, resolved stress symptoms, decreased physiological arousal, mastery, insight) needs to be conducted. In addition, given the heterogeneity of MUS, it is likely only a subgroup of patients will benefit from any single treatment approach. Therefore, future research should examine patient characteristics that may be potential moderators of treatment outcomes, such as baseline assertiveness, ambivalence over emotional expression, and emotional processing abilities. This can help better direct clinical care by tailoring treatment to the needs of different individuals. Such studies might also include measures of nonspecific factors, or homework adherence, to determine if these factors might account for the data.

In addition, only a one-session "dosage" of treatment was tested; however, it is possible that a longer intervention (e.g. 3-5 sessions) would result in stronger effects. One session is likely not enough for participants to enhance their emotional awareness, release inhibited affect, and successfully resolve emotional conflicts. Therefore, researchers should consider testing a longer version of this intervention to identify the most beneficial length of treatment. Also, readiness to change might be conceptualized and tested as a moderator instead of an outcome measure. In addition, it is also important to consider the possibility that a participant may have more than one emotional conflict that needs to be addressed. For example, in this study one participant noted

that she was verbally and physically abused by her adoptive parents, and also raped by a stranger as an adult. These two scenarios brought up different sources of conflict for her that needed to be addressed. In this case, multiple sessions might be needed to resolve the patient's underlying issues. However, adding additional treatment visits may enhance participant burden and/or increase the chance of attrition. To meet the needs of the participants, researchers could consider adding a booster session 1 month after final treatment session to help the participant continue to work through issues that linger.

It is also important examine the impact of these interventions in different samples. Many patients with MUS do not seek medical treatment, or they stop consulting with medical providers because current treatments are often unhelpful. Some argue that these medically unexplained syndromes are all related (Yunus, 2008). It may be advantageous to discern if patients who have one condition (e.g., IBS) would respond differently than patients with comorbid conditions, or whether a longer dose of the intervention might be needed for patients with comorbid conditions. It might also be informative to test how these effects differ when tested in a different setting, including specialty clinics, where patients are highly distressed.

Although the focus of this study was on piloting a novel one-session interview for MUS in primary care, it is worth considering how this technique may work in conjunction with other established approaches that are already used in these settings. There is a movement towards more integrated, multicomponent treatment packages in research and practice. A similar approach could be used for this population. For example, a recent multicenter, randomized, active-controlled study compared the efficacy of a CBT enriched with an emotion regulation training (ENCERT) with a conventional CBT for MUS (Kleinstäuber, Gottschalk, Berking, Rau, & Rief, 2016). Study findings showed that the combination is more efficacious than traditional cognitive

behavior approaches in patients with MUS, and concluded that enriching CBT with transdiagnostic therapeutic strategies addressing emotion regulation is a promising and new approach to target not only somatic symptom coping but also comorbid mental disorders (Kleinstäuber et al., 2016). One might develop a unified protocol, which combines both symptom-management techniques (e.g., relaxation exercises) and emotional processing components to be used by psychologists in primary care. An integrated approach may be more patient-centered, enhance effect sizes, and reach a greater number of people, who have different intervention needs.

In conclusion, these findings provide preliminary evidence that a single, 90-minute interview that targets patients' awareness about the links between their stress and health, and engages them in an emotional experiencing and expression exercise, reduces pain severity, interference, insomnia, and psychological symptoms in primary care patients with MUS. Given that psychologists in primary care often focus only on psychiatric diagnoses and brief symptom management approaches, these findings provide preliminary evidence for the importance of integrating an emotional component in the assessment and intervention with MUS in primary care. In addition, it has the potential to be a beneficial alternate approach to more traditional cognitive and behavioral approaches that focus on emotional down regulation or symptom management, for patients with MUS. These findings may inform evidence-based practice, improve health outcomes for patients, and reduce healthcare utilization and costs for a host of health conditions.

APPENDIX A: Interview Protocol

1. Have patients complete **"Before Session Ratings"**
2. **Discuss ground rules for sessions *(5 min)***

    a. There are many things to cover each session, and I will keep you on track
    b. Remind the participant about confidentiality & audio recording (for supervision purposes)
    c. Remind them that session will run for 90mins, verify ability to participate

3. **Introduction *(5 min)***

    a. Rationale
    - Remind them that they're here because they reported symptoms during their intake (this won't apply for Jen); *our role is helping you understand the potential role of stress on your health; want to see what role, if any, stress plays in your health*

    b. Meta-communication
    i. We are going to go through a variety of questions about your life, including questions about your health and stressful life experiences; some of these might be difficult to share and some that might not be. You don't know me well, or how I might respond, but I encourage you to be honest and open with me. I know that remembering when a symptom started and how regularly it occurred can be difficult to remember, so please just try your best to give the most accurate response you can.

4. **Health History *(10 mins)***

Goal: Get an overview of the participant's health history, including the onset and development of symptoms and/or medical conditions

- *Let's start by doing a brief overview of your health history* (have a sheet of paper to fill out)
- From birth – now (with approximate ages)

a. Create a timeline with patient

i. Health issues/symptoms
Tell me about what kinds of health problems you've had in your life, starting in childhood until now.

- Go over checklist of things they might have missed
    - Abdominal pains
    - IBS
    - Headaches (tension, migraine)
    - Unexplained rashes
    - Insomnia or trouble sleeping

- Fibromyalgia
- Chronic pain
- Pelvic pain
- PMS
- Fatigue
- TMJ

5. **Stress History (30 minutes)**
   Goal: to help the patient develop an awareness that their physical symptoms are linked to their stress/emotions

   Stressful life experiences, including mental health issues (anxiety/dep):

   Introduce the task: *I want you to go through their life, from birth to now, telling me any stressful events or difficult experiences that you have had*

   Meta-communication about comfort of sharing:
   I know that many of these questions can be difficult to share and they might be questions that you are not normally comfortable sharing with other people in your life. It is normal to feel somewhat uncomfortable sharing information about really difficult experiences in your life.

   (How are you feeling about sharing with me today?)

   (What are your concerns about sharing with me today?)

   (I can understand if you feel reluctant to tell me some things, but I really encourage you to give it a try, even if it is difficult or embarrassing or upsetting.)

   After they share, go through the checklist for issues they may have forgotten:

   I want you to know that many people have gone through these experiences. I will ask you about some specific events and situations that we know are not uncommon experiences for people and we want to know better what your experience with these situations is.

   - Checklist: have you ever experienced any of the following:
     - Serious disaster (war, explosion, earthquake)
     - Childhood maltreatment (neglect, not fed or clothed, foster care)
     - Violence between family members (e.g., hitting, kicking, slapping, punching)?
     - Divorce (self or parents)
     - Emotionally abused or neglected (shamed, embarrassed, ignored, or repeatedly told that you were “no good”)?
     - Abortion or miscarriage
     - Private health issues –STDs

- Has a baby or child of yours ever had a severe physical or mental handicap?
- Care-giving for someone close to you who had a severe physical or mental handicap
- Abused or physically attacked (not sexually) by someone you knew? Someone you didn't know?
- Harassed by sexual remarks, jokes, or demands for sexual favors
- Touched or made to touch someone else in a sexual way because he/she forced you in some way
- Have sex (oral, anal, genital) when you didn't want to because someone forced you in some way
- Have any of the events mentioned above ever happened to someone close to you so that even though you didn't experience it yourself, you were seriously upset by it?
- Has someone close to you died (expectedly or unexpectedly)?

- **Secrets?** Conflicts or private struggles with things?
  I would like you to share something you never shared before or haven't shared with me, maybe something private like a secret. You don't know me well, or how I might respond, but I encourage you to be honest and open with me. I can understand if you feel reluctant to share that with me, but I really encourage you to give it a try, even if it is difficult or embarrassing or upsetting.

i. Identifying core conflicts using the checklist

- Ask generally, *what do you struggle with or have a hard time expressing? What do you generally avoid? What do you feel pressured to do or say? What are you conflicted over?*
  After they share, go over examples from the list.
- <u>Checklist</u>:

<u>Private Conflicts:</u>

- Conflicts or struggles over sexual behaviors, identity or relationships
- Not fitting in or feeling ostracized (being teased or picked on, being shy and reserved, not being athletic or popular)
- Feeling inferior to siblings or other relatives (not as beautiful, funny, athletic, interesting, accomplished)
- Resentment and/or anger towards family members, religious leaders, neighbors

<u>Psychological Consequences:</u>

- Feeling pressure to succeed or be perfect
- Disappointing people
- Getting too close to people
- People, memories, or things that you avoid?
- Loss and abandonment (losing a parents or child, divorce)

- Never feeling loved or cared for
- Not trusting others; avoiding being too close, touching or too connected with others
- Never feeling good enough, having to "earn" love from parents, feeling criticized much of the time
- Learning to be anxious, worried, or insecure

6. **Experiential Component (30 minutes)**
    - Applaud participants for recognizing conflict*: Thank you for sharing those experiences with me, that was brave of you. The way these conflicts show up is normally in what you say and do with others in your life*

Rationale

- Rationale of two core domains: dominance (independence, agency, assertiveness, power) and attachment (love, connecting, trust): *We all have two core needs. First, to be loved, accepted and cared for; to be able to trust and connect to someone. Second, we have a need to be independent, strong, even powerful; to take care of and protect ourselves. These two needs show up in our important relationships.*
- *Ideally, people should be free to express both needs, but what usually happens it is hard, at least in some relationships.*

SYMPTOMS: *How would you rate your physical symptoms right now, on a scale from 0-10; 0(no pain), 10(worst pain).*

Domain I: Communion

Q: How can you express sadness, or love, or longing for someone?

- What words or sayings can you share that help bring you closer to another person, to connect with them?
    - I'm sorry about what I did to you.
    - I don't want to lose you.
    - I want to be close to you.
    - I love you.
    - Thank you for doing that for me.
    - I was wrong. (You were right.)
    - I don't want to hurt you.
    - I want you and me to have a closer, more genuine relationship.
    - You really are important to me.

Q: What tone do you have in your voice?

- It should be connecting, genuine, soft

Q: What posture do you show with your body? Your face?

- Demonstrate such postures…open body and arms…face soft

Domain II: Agency

Q: What are some words that we use when we mean that we are angry?

- Generate list of words ranging "intensity" from very low (e.g., annoyed) to very high (enraged, furious)

Q: What posture can you use to show anger or strength?

- Standing tall, proud, arms crossed
- Standing akimbo (hands on hips/ defensive posture)
- Pointing at someone exercise
- Strong / angry gestures (e.g., flipping the bird, thumbing the nose, etc.)

- Close your eyes and imagine someone trying to hurt your body….or take your children….or touch you in a way that you don't want.
  - What does your body want to do? Your hands?
  - Picture yourself pushing that person very hard, Punching that person, Choking that person

- How about facial expressions of anger? What do they look like?

  - Note: You cannot smile and be angry: smiling is usually a barrier or defense
  - How about tears instead of anger? Usually they are learned ways to reduce your anger and avoid hurting someone.

Q: How can your voice show anger?

- Voice loudness: Many people have trouble yelling …help them do it, escalating the volume and intensity
  - Try "NO!" and increase in volume and intensity
  - Try "I WILL NOT" and do the same thing.
  - Try: I AM MAD AT YOU!

PROMPTS: *How is that for you? How hard or easy?*
SYMPTOMS: *How would you rate your physical symptoms right now, on a scale from 0-10; 0(no pain), 10(worst pain).*

Specific Demonstrations, ASK:

Rationale:

- *Stress is very often having these two needs conflict with each other, or be suppressed. Stress is often being trapped when you have these important things to be expressed, but you feel stuck—that it is wrong or dangerous to express them.*

- *You are doing these things in this private meeting, this doesn't mean that we are encouraging you to do them in their relationships. But that the goal here is to have you "try on" new ways of expressing yourself*

- *Then,* ***how does this apply to key people in your life****?*
- ***Show me what it looks like to be X, Y with person Z***
- *Is there a part of you what would like to express X and Y to Z*
- *I'd like to do a test run of how you can express some of these important emotions*
- Take them through expressing their emotions to one or two important people who they have conflict with
- Identify a conflicted relationship from the person's stress interview.

PROMPTS: *How is that for you? How hard or easy?*
SYMPTOMS: *How would you rate your physical symptoms right now, on a scale from 0-10; 0(no pain), 10(worst pain).*

7. **Wrap up: (10 minutes)**
   - What have you discovered about yourself? Your symptoms? The connections?
   - How did you feel about the interview? What were your reactions? Likes/dislikes?
   - Give them feedback, offer it as a hypothesis: *This is an area of strength…etc, Seems like expression of anger is anxiety provoking for you, that's pretty common, may be beneficial for you to work on it and get more comfortable about*
   - *For many people, the stress of keeping things suppressed actually contributes to their physical symptoms, and that relief from symptoms happens when they are able to express their genuine feelings. This can be done in writing, privately when you are alone, and even directly to a person, though when you do that, you usually need to communicate more gently, both of your needs (love and power)*

8. Complete **"Post-Session Ratings"**

APPENDIX B: Measures

Sociodemographic Form

Please answer the following questions. Complete the blanks or check the category that best describe your situation.

1. Sex: Male/ Female

2. Age: _____

3. What is the highest level in school that you completed?
   ___ Less than HS or GED _____ Highest Grade Completed
   ___ HS or GED (=12yrs)
   ___ Some college, but less than an associate's degree (=13yrs)
   ___ Associate's degree or two years of college (=14)
   ___ College degree [e.g. BA/BS] or four years of college (=16)
   ___ Master's degree (=18 yrs)
   ___ Doctoral Degree (=20 yrs)

4. Ethnic Category:
   _____ Hispanic or Latino
   _____ Not Hispanic or Latino

5. Racial Category:
   _____ American Indian or Alaskan native
   _____ East Asian (e.g. Japanese, Chinese)
   _____ South Asian (e.g. Indian, Pakistani)
   _____ Native Hawaiian or Other Pacific Islander
   _____ Black of African American
   _____ White or European American
   _____ Middle Eastern or Arab
   _____ Other (please describe: _____)

6. What is your current marital status:
   ___ Married
   ___ Separated
   ___ Divorced
   ___ Widowed
   ___ Never married
   ___ Living with a partner in a committed relationship

   Duration of above status: _____ (round to closest year)

7. What is your current employment status?
   ___ Homemaker
   ___ Unemployed, but seeking employment
   ___ Unemployed, not seeking employment
   ___ Retired
   ___ On disability
   ___ Full-time employed

___ Part-time employed
___ Full-time student only

8. What is your household income?
___ Less than $10,000
___ $10,000 to $14,999
___ $15,000 to $24,999
___ $25,000 to $34.999
___ $35,000 to $49,999
___ $50,000 to $74,999
___ $75,000 to $99,999
___ $100,000 to $149.999
___ $150,000 to $199,999
___ $200,000 or more

9. What is your current occupation?
_____

10. Are you currently receiving disability or workman's compensation?
___ Yes
___ No
If yes, when did you start receiving disability or workman's compensation? _____

11. Are you currently in counseling or psychological therapy? _____ Yes _____ No
For what? _____

12. Have you ever had counseling or psychological therapy? _____ Yes _____ No
For what? _____

MEDICAL INFORMATION AND HISTORY

1. Primary diagnosis: _____
2. Onset of those symptoms: _____ *[record year]*
3. Date of First Diagnosis: _____ *[record year]*
4. Have you experienced pain or symptoms today? _____Yes _____No

5. Is your health affected by any of the following medical problems?

_____ Heart disease
_____ Diabetes
_____ Hypertension
_____ Chronic lung disease
_____ Cancer
_____ Gout
_____ Stroke
_____ Syncope/Fainting
_____ Kidney disease
_____ Liver disease
_____ Ulcer or other stomach disease
_____ Psychiatric illness or mental disorder
_____ Alcohol or drug use

_____Lupus
_____Scleroderma
_____Rheumatoid Arthritis
_____Headaches
_____Migraine?
_____Asthma
_____Irritable Bowel Syndrome
_____Crohn's Disease
_____Ulcerative Colitis
_____Chronic Pelvic Pain
_____Interstitial Cystitis
_____Vulvodynia
_____ Other

Other Medical Conditions? _____.

6. **Height** (in feet and inches): _____. **Weight** (in pounds) : _____.

ALTERNAIVE TREATMENTS INFORMATION

Many people try a lot of different things to help with their health. Tell me if you have ever used or tried each of the following things to improve your symptoms.

	Ever?	Past month?
Eating healthier or changing your nutrition …….		
Eating herbal remedies ……		
Using over-the-counter or non-prescription medications ……		
Using street drugs such as marijuana, cocaine, or others ……		
Praying, reading the Bible, or other religious things by yourself…		
Attending religious services (includes revival, laying on of hands, etc.) ……		
Acupuncture …….		
Biofeedback ……		
Talking with a counselor or psychotherapist ……		
Physical therapy ……		
Exercise ……		
Imagery, relaxation, or meditation ……		
Support group ……		
Magnets or copper bracelets …….		
Other: _____		

What medications are you currently taking?

Name of medication Indication (for what?) Frequency

What vitamins and/or supplements are you currently taking?

Name of supplement Indication (for what?) Frequency

PHYSICAL SYMPTOMS

PHQ-15

During the past week, how much have you been bothered by any of the following problems?

	Not at all bothered (0)	Bothered a little (1)	Bothered a lot (2)
a. Stomach pain	☐	☐	☐
b. Back pain	☐	☐	☐
c. Pain in your arms, legs or joints (knees, hips, etc.)	☐	☐	☐
d. Menstrual cramps or others problems with your period **(women only)**	☐	☐	☐
e. Headaches	☐	☐	☐
f. Chest pain	☐	☐	☐
g. Dizziness	☐	☐	☐
h. Fainting spells	☐	☐	☐
i. Feeling your heart pound or race	☐	☐	☐
j. Shortness of breath	☐	☐	☐
k. Pain or problems during sexual intercourse	☐	☐	☐
l. Constipation	☐	☐	☐
m. Nausea, gas, or indigestion	☐	☐	☐
n. Feeling tired of having low energy	☐	☐	☐
o. Trouble sleeping	☐	☐	☐

BRIEF PAIN INVENTORY

1. Please rate your pain by circling the one number that best describes your pain at its *worst* in the last week.

   0 1 2 3 4 5 6 7 8 9 10

   No pain — Pain as bad as you can imagine

2. Please rate your pain by circling the one number that best describes your pain at its *least* in the last week.

   0 1 2 3 4 5 6 7 8 9 10

   No pain — Pain as bad as you can imagine

3. Please rate your pain by circling the one number that best describes your pain on the *average* for the last week.

   0 1 2 3 4 5 6 7 8 9 10

   No pain — Pain as bad as you can imagine

4. Please rate your pain by circling the one number that tell how much pain you have *right now.*

   0 1 2 3 4 5 6 7 8 9 10

   No pain — Pain as bad as you can imagine

For the next set of questions, choose the one number that describes how, during the past week, pain has interfered with the following activities. Please use the 0 to 10 scale, where a 0 means that "pain does not interfere with that activity" and a 10 means that "pain completely interferes."

Does not interfere										**Completely interferes**
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

a) General Activity……0 1 2 3 4 5 6 7 8 9 10

b) Mood……0 1 2 3 4 5 6 7 8 9 10

c) Mobility (ability to get around)……0 1 2 3 4 5 6 7 8 9 10

d) Normal Work (includes both work outside the home and housework)

……0 1 2 3 4 5 6 7 8 9 10

e) Relations With Other People……..……..0 1 2 3 4 5 6 7 8 9 10

f) Sleep……..0 1 2 3 4 5 6 7 8 9 10

g) Enjoyment Of Life……..…..0 1 2 3 4 5 6 7 8 9 10

h) Self Care (taking care of your daily needs)…….....0 1 2 3 4 5 6 7 8 9 10

i) Recreational Activities……...0 1 2 3 4 5 6 7 8 9 10

j) Social Activities……0 1 2 3 4 5 6 7 8 9 10

k) Communication With Others……..……..0 1 2 3 4 5 6 7 8 9 10

l) Learning New Information or Skills……..0 1 2 3 4 5 6 7 8 9 10

Global Symptom Rating

1. How would you rate your symptoms now?

☐ Markedly worse
☐ Moderately worse
☐ Slightly worse
☐ No change
☐ Slightly improved
☐ Moderately improved
☐ Markedly improved

BRIEF SYMPTOM INVENTORY

Below is a list of problems and complaints that people sometimes have. Please circle the response that best describes how much discomfort that problem has caused you during the past 7 days INCLUDING TODAY. Please do not skip any items.

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Nervousness or shakiness inside	0	1	2	3	4
2. Thoughts of ending your life	0	1	2	3	4
3. Suddenly scared for no reason	0	1	2	3	4
4. Feeling lonely	0	1	2	3	4
5. Feeling blue	0	1	2	3	4
6. Feeling no interest in things	0	1	2	3	4
7. Feeling fearful	0	1	2	3	4
8. Your feelings being easily hurt	0	1	2	3	4
9. Feeling that people are unfriendly	0	1	2	3	4
10. Feeling inferior to others	0	1	2	3	4
11. Feeling hopeless about the future	0	1	2	3	4
12. Feeling tense or keyed up	0	1	2	3	4
13. Feeling very self-conscious with others	0	1	2	3	4
14. Spells of terror or panic	0	1	2	3	4
15. Feeling so restless that you couldn't sit still	0	1	2	3	4
16. Feelings of worthlessness	0	1	2	3	4

Change Assessment Questionnaire

0 = Strongly Disagree
1 = Disagree
2 = Undecided
3 = Agree
4 = Strongly Agree

	SD	D	U	A	SA
1. The best thing I can do is find a doctor who can figure out how to get rid of my symptoms once and for all.	0	1	2	3	4
2. Even if my symptoms don't go away, I am ready to start changing how I deal with it.	0	1	2	3	4
3. I am testing out some stress management techniques to manage my symptoms better.	0	1	2	3	4
4. My symptoms are a medical problem and I should be dealing with physicians about it.	0	1	2	3	4
5. I realize now that it is time for me to come up with a better plan to cope (e.g. stress management techniques) with my symptoms.	0	1	2	3	4
6. I use what I have learned to help keep my symptoms under control.	0	1	2	3	4
7. All of this talk about how to manage stress better is a waste of time.	0	1	2	3	4
8. I am beginning to wonder if I need to get some help to develop skills for dealing with my symptoms.	0	1	2	3	4
9. I have started to come up with strategies to help myself control my symptoms.	0	1	2	3	4
10. I'm confident that I can deal with my pain or other symptoms on my own.	0	1	2	3	4
11. I believe that my emotions and stress are the major cause of my symptoms.	0	1	2	3	4
12. I think that psychological counseling might be helpful to me to reduce my stress.	0	1	2	3	4
13. I plan to have psychological counseling to help me reduce my stress.	0	1	2	3	4
14. I am satisfied with the medical care that I am receiving at the (Women's Urology Center; Crittenton Family Medicine Clinic).	0	1	2	3	4
15. I recommend that family or friends come to this clinic for their medical care.	0	1	2	3	4

Symptom Interpretation Questionnaire

Listed below are conditions you may or may not have ever experienced. For each condition, please circle the letter next to each reason or group of reasons that corresponds to how much that might explain your condition. Please check every item for each question. Also, answer whether you have had the condition in the past 3 months by circling A (YES) or B (NO). Please answer all questions.

	A Not at all	B Some-what	C Quite a bit	D A great deal
1. If I experience *pain in my body*, I would probably think that it is because:				
My genetic vulnerability to pain	A	B	C	D
My emotions are out of whack	A	B	C	D
The time of day or the weather	A	B	C	D
Have you had pain in your body in the last 3 months?	A - Yes		B - No	
2. If I experience *several physical symptoms*, I would probably think that it is because:				
My sensitive bodily tissue or makeup	A	B	C	D
I am feeling overwhelmed	A	B	C	D
I exerted too much effort	A	B	C	D
Have you had several physical symptoms in the last 3 months?	A - Yes		B - No	
3. If I had a *prolonged headache*, I would probably think that it is because:				
I am emotionally upset	A	B	C	D
There is something wrong with my muscles, nerves or brain	A	B	C	D
A loud noise, bright light or something else has irritated me	A	B	C	D
Have you had a prolonged headache in the last 3 months?	A - Yes		B - No	
4. If I was *sweating a lot*, I would probably think that it is because:				
I must have a fever or infection	A	B	C	D
I'm anxious or nervous	A	B	C	D
The room is too warm, I'm overdressed or working too hard	A	B	C	D
Have you noticed yourself sweating a lot in the last 3 months?	A - Yes		B - No	
5. If I got *dizzy all of a sudden*, I would probably think it is because:				
There is something wrong with my heart or blood pressure	A	B	C	D
I am not eating enough or I got up too quickly	A	B	C	D
I must be under a lot of stress	A	B	C	D
Have you felt dizzy in the last 3 months?	A - Yes		B - No	

6. If I noticed my *mouth was dry*, I would probably think it is because:

I must be scared or anxious about something	A	B	C	D
I need to drink more liquids	A	B	C	D
There is something wrong with my salivary glands	A	B	C	D
Have you had a dry mouth in the last 3 months?	A - Yes		B - No	

7. If I felt my *heart pounding in my chest*, I would probably think it is because:

I've exerted myself or drunk a lot of coffee	A	B	C	D
I must be really excited or afraid	A	B	C	D
There must be something wrong with my heart	A	B	C	D
Have you noticed your heart pounding in the last 3 months?	A - Yes		B - No	

8. If I felt *fatigued*, I would probably think it is because:

I'm emotionally exhausted or discouraged	A	B	C	D
I've been over-exerting myself or not exercising enough	A	B	C	D
I'm anemic or my blood is weak	A	B	C	D
Have you felt fatigued in the last 3 months?	A - Yes		B - No	

9. If I noticed my *hand trembling*, I would probably think it is because:

I might have some sort of neurological problem	A	B	C	D
I'm very nervous	A	B	C	D
I've tired the muscle in my hand	A	B	C	D
Have you noticed your hands trembling in the last 3 months?	A - Yes		B - No	

10. If I had *trouble sleeping*, I would probably think it is because:

Some kind of pain or physical discomfort is keeping me awake	A	B	C	D
I'm not tired or I had too much coffee	A	B	C	D
I'm worrying too much or I must be nervous about something	A	B	C	D
Have you had trouble sleeping in the last 3 months?	A - Yes		B - No	

11. If my *stomach was upset*, I would probably think it is because:

I've worried myself sick	A	B	C	D
I have the flu or stomach irritation	A	B	C	D
I've had something to eat that did not agree with me	A	B	C	D
Have you had an upset stomach in the last 3 months?	A - Yes		B - No	

12. If I lost my *appetite*, I would probably think it is because:

I've been eating too much or my body doesn't need as much food as before	A	B	C	D

I'm worrying so much that food just doesn't taste good anymore	A	B	C	D
I have some stomach or intestinal problem	A	B	C	D
Have you lost your appetite in the last 3 months?	A - Yes		B - No	

13. If I had a *hard time catching my breath*, I would probably think it is because:				
My lungs are congested from infection, irritation or heart trouble	A	B	C	D
The room is stuffy or there is too much pollution in the air	A	B	C	D
I'm over-excited or anxious	A	B	C	D
Have you had a hard time catching your breath in the last 3 months?	A - Yes		B - No	

14. If I noticed *numbness or tingling in my hands or feet*, I would probably think it is because:				
I'm under emotional stress	A	B	C	D
There is something wrong with my nerves or blood circulation	A	B	C	D
I am cold or my hand or foot went to sleep	A	B	C	D
Have you had numbness or tingling in your hands or feet in the last 3 months?	A - Yes		B - No	

15. If I was *constipated or irregular*, I would probably think it is because:				
There is not enough fruit or fiber in my diet	A	B	C	D
Nervous tension is keeping me from being regular	A	B	C	D
There is something wrong with my bowels or intestines	A	B	C	D
Have you been constipated or irregular in the last 3 months?	A - Yes		B - No	

Health Care Utilization Disability Questionnaire

ID Number: _____

Phase: Pre-treatment 1 - Follow-up 2- Follow-up

Determine what the date was 3 months ago from today. Spend a few moments to recall what you have been doing since then, especially thinking about your health. Then answer these questions.

During the last 3 months, how many times have you:
Seen a physician or other health care professional for treatment of illness or symptoms? ___
Seen a physician or other health care professional for a regular checkup or preventive care? ___
Telephoned a physician or other health care professional, but did not visit? ___
Been to an emergency room? ____ (For what: _____)
Talked to a psychological counselor or therapist? ___

During the past 3 months, on how many days have you:
Missed any work or school because you were ill? ___
Taken any prescription medication? ___
Taken an over the counter medication for colds, allergies, sinuses, or breathing problems? ___

For the next questions, respond using the scale below:

0 = Never/none 1 = Very little 2 = Moderate amount 3 = Quite a bit 4 = A lot

During the past 3 months, how much cigarette smoking have you done? ___
During the past 3 months, how often have you gotten enough sleep? ___
During the past 3 months, how much physical exercise have you gotten? ___
During the past 3 months, how often have you eaten healthy, nutritious food? ___
During the past 3 months, how much alcohol have you consumed? ___

During the last 3 months, circle a number to rate how much your health has interfered with your daily activities.

0 1 2 3 4 5 6 7 8 9 10
No Interference Unable to carry on any activities

Please rate your health during the last 3 months by making a mark anywhere on the line between Very poor and excellent.

Very poor _____ Excellent

Please circle a number to rate your overall stress level during the last 3 months.

0 1 2 3 4 5 6 7 8 9 10
No Stress Unbearable str

Insomnia Severity Index

Thinking about your CURRENT (i.e., LAST 2 WEEKS) insomnia problem (s):

- ***CIRCLE*** **the number that best describes your answer for each question.**

	None	Mild	Moderate	Severe	Very severe
1. Difficulty Falling asleep	0	1	2	3	4
2. Difficulty staying asleep	0	1	2	3	4
3. Problem waking up too early	0	1	2	3	4

4. How SATISFIED/DISSATISFIED are you with your sleep pattern?

Very satisfied	Satisfied	Moderately Satisfied	Dissatisfied	Very Dissatisfied
0	1	2	3	4

5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all Noticeable	A Little	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

6. How WORRIED/DISTRESSED are you about your current sleep problem?

Not at all Worried	A Little	Somewhat	Much	Very Much Worried
0	1	2	3	4

7. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.)?

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

SWLS

Below are five statements with which you may agree or disagree. Using the scale below, indicate your agreement with each item by placing the appropriate number on the line preceding that item. Please be open and honest in your responding.

1 = Strongly disagree
2 = Disagree
3 = Slightly disagree
4 = Neither agree nor disagree
5 = Slightly agree
6 = Agree
7 = Strongly agree

____ 1. In most ways my life is close to my ideal.
____ 2. The conditions of my life are excellent.
____ 3. I am satisfied with my life.
____ 4. So far, I have gotten the important things I want in life.
____ 5. If I could live my life over, I would change almost nothing.

APPENDIX C: Recruitment Script and Screening Questions

The text of this Recruitment Script is essentially the wording from the consent form, which we feel contains all of the elements that patients should know about the study. Thus, the following will be stated over the phone or in person.

PART I: IN-PERSON

** If patient sees the flyer, then contacts the researcher in-person at the clinic to express interest in learning more about the study: Hi <*insert the name of the individual*>, thank you for your interest in our study, "Stress and Health Interview for Primary Care Patients with Medically Unexplained Symptoms". Let me first ask you some basic questions to see if you are eligible to participate in the study. If so, we can go over the full study procedures [PART-II] and the written consent form for the study. *Individuals will then be given the Information Sheet for answering basic screening questions.*

For individuals who contact us by phone, we will read the information sheet and ask the pre-screening questions below. Then script in PART II will be used for all interested participant who meet the basic pre-screening criteria.

Pre-Screening Questions:

1. *During the past 4 weeks, how much have you been bothered by any of the following problems? On a scale of 0 (not at all bothered); 1(bothered a little); 2 (bothered a lot)*

- *Stomach pain*
- *Back pain*
- *Pain in your arms, legs or joints (knees, hips)*
- *Menstrual cramps or other problems with your period (women only)*
- *Headaches*
- *Chest pain*
- *Dizziness*
- *Fainting spells*
- *Feeling your heart pound or race*
- *Shortness of breath*
- *Pain or problems during sexual intercourse*
- *Constipation*
- *Nausea, gas or indigestion*
- *Feeling tired or having low energy*
- *Trouble sleeping*

If eligible: Great! Are you interested in learning more about our study?

PART II: RECRUITMENT SCRIPT

THIS SCRIPT IS GOING TO BE USED IN PERSON AND ON THE PHONE AFTER COMPLETING THE PHQ-15 FOR PARTICIPANTS WHO QUALIFY.

** Hi, my name is <insert the name of the research assistant> and I work with the research team at Wayne State University, who are conducting a research study for patients with medically unexplained symptoms. The study is being conducted by Mark Lumley, Ph.D., of the Department of Psychology at Wayne State University. The purpose of the study is to conduct a stress and health interview to learn about your health history, the role of stress in your life and its contributions, if any, to your symptoms and health.

If you agree to take part in this research study, you will first complete a one-hour evaluation session at home during which you will fill out questionnaires online about your current physical symptoms, your mood, your functioning, and your attitudes and beliefs. After the first evaluation session, you will be randomly assigned (like by the flip of a coin) to one of two conditions. You have a 2 out of 3 chance of being assigned to the Interview condition, and a 1 out of 3 chance of being assigned to a Waiting condition.

If you are assigned to the Interview condition, you will be asked to return to the clinic within the next week for a 90-minute interview. During this session, you will meet privately with an interviewer. This interview will review your health history, stressful events and experiences in your life, explore links between your stress and health, and examine how you deal with your emotions and express them. At the beginning and end of the interview, you will complete a brief measure of your mood and symptoms. In addition, your blood pressure will be measured before, in the middle, and after the interview using an automated Dinamap blood pressure monitor. The session with the interviewer will be audiorecorded for supervision purposes. Six weeks after you complete the baseline questionnaires, you will be asked to complete the same questionnaires as you did at the first session.

If you are assigned to the Waiting condition, you will wait for the interview until after your evaluation session that is held at 6 weeks from the baseline questionnaires. At that time, you will be given the option to participate in the interview session.

By taking part in this study you might learn more about your health and links between your stress and your physical symptoms. You may also learn a new approach to reduce your stress, which in turn may improve your symptoms. However, we do not know whether or how much your symptoms may improve. Additionally, information from this study may benefit other people with medically unexplained symptoms.

By taking part in this study, you may experience the following risks. The interview may be briefly uncomfortable or upsetting or may cause you to feel some anxiety. Finally, there is a risk that the confidentiality of your information could be lost under the following circumstances: If you are thought to be at risk for self-harm or harming another, or if at any time during the study there is a concern that child abuse or elder abuse has possibly occurred, or if at any time during the study there is a disclosure of illegal criminal activities, illegal substance abuse, or violence, then this information may be released to the appropriate authorities. There may also be risks involved in taking part in this study that are not known to researchers at this time.

The alternative to participating in this study is to not participate. This study does not require you to change your usual medical care. Therefore, regardless of whether or not you participate, you should maintain regular medical care with your physician.

In the unlikely event that this research related activity results in an injury; no reimbursement, compensation or free medical care is offered by Wayne State University.

The interview will be provided at no cost to you. If you are in the interview group, you will be paid $10 for each evaluation session that you complete, and $20 for completing the interview. If you are in the waiting group, you will be paid for each evaluation session that you complete, at $20 for each session; thus, you can be paid up to a total of $40.

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records only by a unique code number. Information that identifies you personally will not be released without your written permission. All data and videotapes will be kept in your study file until after 5 years or until the study is completed, whichever is longer, and then will be destroyed. We will not release any information about you to your physician or to others unless you request us to do so.

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study, you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with the Family Medicine Clinic or Wayne State University or its affiliates, or other services you are entitled to receive. The investigator, or the sponsor, may stop your participation in this study without your consent.

What questions do you have?

Are you interested in participating?

If interested: Great, I have a few more questions that I would like to ask you to see if you qualify.

1. Do you have any of the following conditions that could account for the elevated physical symptoms?

    - Autoimmune disease
    - Gastrointestinal disease
    - Bodily injury
    - Serious infection
    - Cancer
    - Heart disease, COPD, post-stroke

2. Do you have any physical or mental health problems that may prevent you from being able to participate in the study?

    a. Do you have schizophrenia or bipolar disorder?
    YES NO

    b. Do you have dementia or any mental impairment?
    YES NO

3. English your first language? (If not, can you read, write, and speak English fluently?)
    YES NO

4. Are you currently in another clinical research trial of an intervention for you physical symptoms?
    YES NO

If eligible: Great! Do you have the time to participate in this study and attend one interview session if you are assigned to it?

If the patient meets the study criteria and is interested and able to participate:

Great! Let's set up a time for you to receive your questionnaires.

APPENDIX D: Consent Form

Interview for Medically Unexplained Symptoms

Behavioral Research Informed Consent
Title of Study: Stress and Health Interview for Primary Care Patients with Medically Unexplained Symptoms

Principal Investigator (PI): Mark A. Lumley, Ph.D.
Department of Psychology, Wayne State University
(313) 577-2247

Purpose

You are being asked to be in a research study of an interview for patients with medically unexplained symptoms because you have reported physical symptoms not clearly due to a disease or injury. This study is being conducted by Wayne State University at the Family Medicine Clinic. The estimated number of study participants to be enrolled at the Family Medicine Clinic is about 120. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, we are conducting a stress and health interview to learn about your health history, the role of stress in your life and its contributions, if any, to your symptoms and health.

Study Procedures

If you agree to take part in this research study, you will first complete a one-hour evaluation session at home during which you will fill out questionnaires online about your current physical symptoms, your mood, your functioning, and your attitudes and beliefs. After the first evaluation session, you will be randomly assigned (like by the flip of a coin) to one of two conditions. You have a 2 out of 3 chance of being assigned to the Interview condition, and a 1 out of 3 chance of being assigned to a Waiting condition.

If you are assigned to the Interview condition, you will be asked to return to the clinic within the next week for a 90-minute interview. During this session, you will meet privately with an interviewer. This interview will review your health history, stressful events and experiences in your life, explore links between your stress and health, and examine how you deal with your emotions and express them. At the beginning and end of the interview, you will complete a brief measure of your mood and symptoms. In addition, your blood pressure will be measured before, in the middle, and after the interview using an automated Dinamap blood pressure monitor. The session with the interviewer will be audiorecorded for supervision purposes. Six weeks after you complete the baseline questionnaires, you will be asked to complete the same questionnaires as you did at the first session.

If you are assigned to the Waiting condition, you will wait for the interview until after your evaluation session that is held at 6 weeks from the baseline questionnaires. At that time, you will be given the option to participate in the interview session.

Benefits

medical care is offered by the Family Medicine Clinic or Wayne State University. If you think that you have suffered a research related injury, contact Dr. Lumley right away at (313) 577 – 2247.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.] may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiorecordings of you will be used for research or educational purposes, your identity will be protected or disguised. All data and audiotapes will be kept in your study file until after 5 years or until the study is completed, whichever is longer, and then will be destroyed.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study, you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with the Family Medicine Clinic or Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because you did not follow the instructions to take part in the study

Questions

If you have any questions about this study now or in the future, you may contact Dr. Mark Lumley or one of his research team members at the following phone number: (313) 577–2247. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. In the event you suffer a research related injury, you may contact the study principal investigator, Dr. Mark Lumley, at (313) 577-2247. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

Interview for Medically Unexplained Symptoms

By taking part in this study you might learn more about your health and links between your stress and your physical symptoms. You may also learn a new approach to reduce your stress, which in turn may improve your symptoms. However, we do not know whether or how much your symptoms may improve. Additionally, information from this study may benefit other people with elevated physical symptoms.

Risks

By taking part in this study, you may experience the following risks. The interview may be briefly uncomfortable or upsetting, or may cause you to feel some anxiety.

Although information will be kept confidential, there are some instances where we are obligated to report our concerns to the authorities. The following information must be released/reported to the appropriate authorities if at any time during the study there is concern that:

- child abuse or elder abuse has possibly occurred
- you have a reportable communicable disease (i.e., certain sexually transmitted diseases or HIV)
- you disclose illegal criminal activities, illegal substance abuse or violence

Additionally, the blood pressure cuff will inflate every few minutes and may be bothersome, but it automatically deflates and does not cause damage. If you cannot tolerate the pressure, let the researcher know and they will remove the blood pressure cuff. Finally, because we are recording your name and other identifying information, there is a risk of a breach or loss of confidentiality. Finally, there may also be risks involved from taking part in this study that are not known to researchers at this time.

Alternatives

An alternative is not to participate in this study. You can also obtain assessments and diagnostic interviews from practitioners in the community, and we encourage you to consult with your physician about this.

Study Costs

Other than transportation, there is no cost to you for participating in this study.

Compensation

You will be paid $10 for completing the baseline questionnaire, $20 for completing the interview session, and $20 for completing the follow-up questionnaire; thus, you can be paid up to a total of $50.

Research Related Injuries

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Care for such will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free

Interview for Medically Unexplained Symptoms

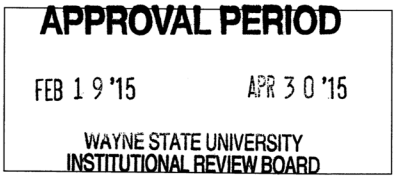
Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Signature of participant / Legally authorized representative *	Date
Printed name of participant / Legally authorized representative *	Time
Signature of witness**	Date
Printed of witness**	Time
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time

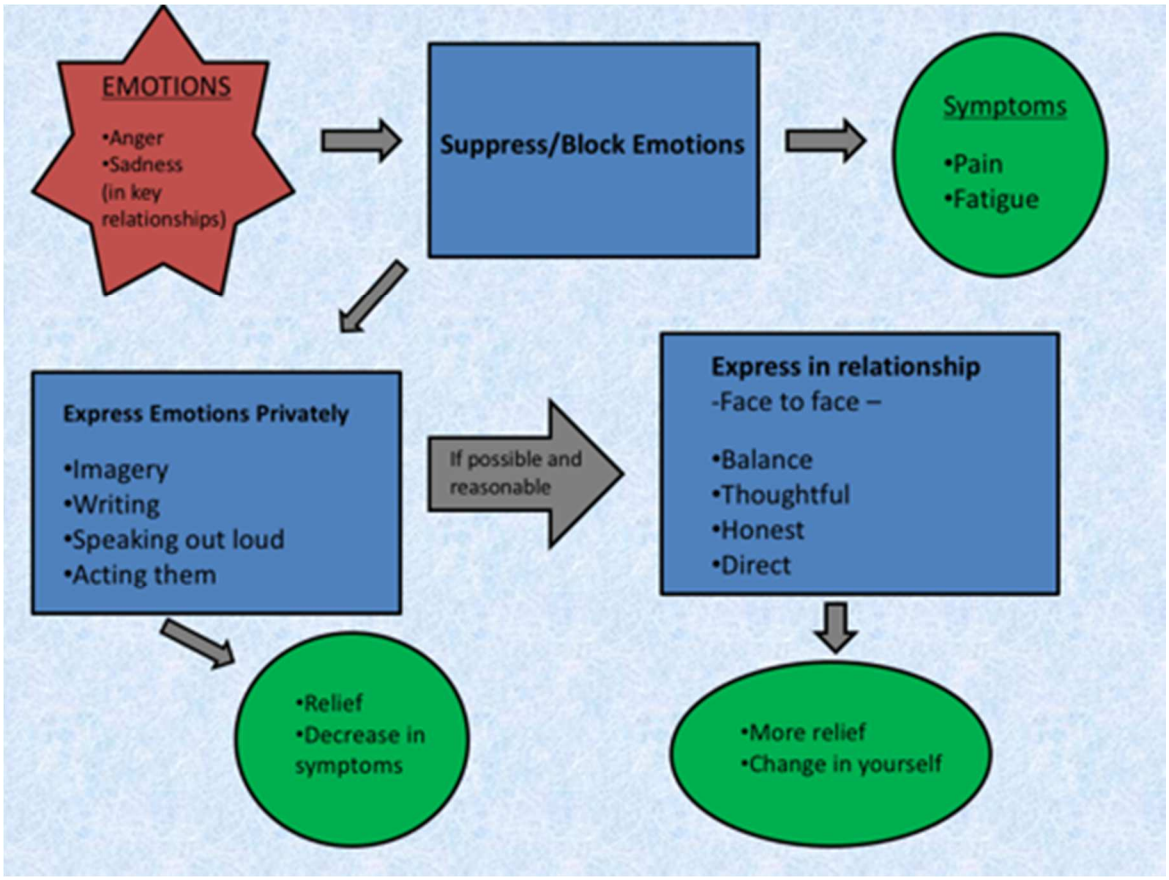
*Remove LAR reference if you don't intend to consent participants that have or may have a LAR.

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).



Signature of translator	Date
Printed name of translator	Time

APPENDIX E: Study model that was given to patients



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ABSTRACT

STRESS AND HEALTH INTERVIEW FOR PRIMARY CARE PATIENTS WITH MEDICALLY UNEXPLAINED SYMPTOMS: A RANDOMIZED TRIAL

by

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Trauma, stress, and inhibited emotions contribute to pain and physical symptoms. People may disclose stressors and express emotions when encouraged, which may improve their symptoms. We developed an intensive interview aimed at: 1) raising patient awareness about the links between their stress and health; 2) engaging patients in emotional experiencing and expression processes. We tested its effects on patient attributions of their symptoms, in addition to physical and psychological outcomes in primary care patients with Medically Unexplained Symptoms (MUS).

In this study, 75 patients (87% women; 79% White; mean age = 39 years) with MUS (e.g., localized chronic pain, fibromyalgia, irritable bowel syndrome, headaches) were recruited from a family medicine clinic. Participants completed self-report measures of their physical and psychological functioning, in addition to their symptom attributions and motivations to change at baseline and after 6 weeks. Then, participants were randomized (2:1 ratio) to one of two conditions: stress and emotion interview (n = 49) or waitlist control (n = 26) conditions. The interview was a single, 90-minute session in the clinic examination room, in which interviewers

obtained patients' medical and life stress histories. Stress experiences were linked to pain and other health changes over the patients' lives, and then patients were engaged in an experiential exercise to express emotions (e.g., anger, sadness) related to their stressors. Intent-to-treat analyses indicated that the interview condition led to significantly greater reductions in pain severity, pain interference, global psychological symptoms, and specifically reduced depression and interpersonal sensitivity at follow-up, compared to controls. Sleep problems also improved and contemplation to change decreased with the intervention. Contrary to hypotheses, neither global physical symptoms nor symptom attributions changed differentially between conditions over time.

Clinical observations and patient reports indicated that the majority of patients had substantial unresolved victimization, conflict, and/or secrets, which typically had not been disclosed in this setting. Even though patients struggled to express their emotions, they were typically thankful and appreciative of this interview opportunity. Given that no professionals, including psychologists, routinely focus on these emotional issues, these findings provide preliminary evidence for the importance of integrating an emotional component in the assessment and intervention with MUS in primary care.

AUTOBIOGRAPHICAL STATEMENT

Maisa Ziadni completed her undergraduate degree in Psychology and Health Sciences at Guilford College in 2007. She obtained her master's degree in Psychology with a focus on health from Drexel University in 2010. She is completing her PhD in Clinical Psychology, with a minor in Health Psychology, at Wayne State University. Currently, she is a Health Psychology Intern at Rush University Medical Center, in Chicago, Illinois.

As a clinical researcher, Maisa has a strong interest in pain disorders, particularly those that involve central sensitization or augmentation (i.e. fibromyalgia, irritable bowel syndrome, pelvic pain, headaches). Her research has focused on developing and testing novel treatments and identifying individual differences in emotional functioning that might influence how individuals respond to these interventions. She hopes to expand the focus of her research to adapt integrated brief interventions for these patients to real-world specialty care clinics and testing the effectiveness of these interventions. Ultimately, she plans to develop training programs for psychologists and other professionals to improve the adoption and dissemination of evidence-based psychological interventions in routine clinical practice.

Maisa plans to pursue a career as a clinical scientist in an academic medical setting. Next year, Maisa will begin a research fellowship in pain medicine at Stanford Systems Neuroscience and Pain Laboratory at Stanford University in Palo Alto, CA under the direction of Dr. Sean Mackey. During fellowship, she will spend 80% of her time conducting clinically relevant research, and 20% of her time engaging in clinical activities.